EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-01

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2020 Base Option Period Number 3	Support for Lead Based Paint

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2019 To 06/12/2020

Comments:
Initiating Work Assignment on Battelle EPW 16017. The contractor shall provide work plan within 15 business days.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 06/13/2016 To 06/12/2020		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Darlene Leonard (Signature) (Date)		Branch/Mail Code: Phone Number: 202-566-0516 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)		Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name: (Signature) (Date)		Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Jody Gosnell (Signature) (Date)		Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:

Contract Number: EP-W-16-017

Work Assignment Number: 3-01

Title: Support for the Lead-Based Paint Program and Other National Program Chemicals

I. Purpose and Background

The purpose of this Work Assignment is to provide technical support of the implementation of the Renovation, Repair and Painting Program (RRP) as well as all other aspects of the Lead-Based Paint Program and of other priority existing chemicals. This is a continuation of work to extend the performance period that began under the previous work assignment, Work Assignment 2-02 of contract EP-W-16-017. No work shall be duplicated.

Title IV of the Residential Lead-Based Paint Poisoning Prevention Act requires EPA to undertake various actions to reduce the incidence of lead poisoning. These actions include technical studies to support rule making, outreach to the regulated community, outreach to the public and support of the regulatory functions.

Title IV of the Residential Lead-Based Paint Poisoning Prevention Act requires EPA to undertake various actions to reduce the incidence of lead poisoning. Specifically Section 405 (a) says " The Administrator, in cooperation with other appropriate Federal departments and agencies, shall conduct a comprehensive program to promote safe, effective, and affordable monitoring, detection and abatement of lead-based paint and other lead exposure hazards" Section 405 (d) says "the Administrator in conjunction with the Secretary of Health and Human Services…and in conjunction with the Secretary of Housing and Urban development, shall sponsor public education and outreach activities to increase public awareness…"

Throughout the year, EPA provides lead awareness and educational outreach to various audiences. In addition, EPA partners with the Centers for Disease Control and Prevention (CDC) and the Department of Housing and Urban Development (HUD) to collaborate on a theme and develop posters and flyers and other education and awareness tools and events specifically designed to observe National Lead Poisoning Prevention Week (NLPPW). EPA also promotes the Lead Week of Action, a lead awareness effort on an international scale.

Additionally, technical support is needed for other work in the National Program Chemicals Division (NPCD). NPCD is responsible existing chemicals that are ready for hazard management. Currently those chemicals include lead, mercury, formaldehyde, and asbestos. NPCD also has new responsibilities related to manufacturer requests for risk evaluations and for several existing chemicals identified as "high priority" for risk evaluation.

II. Scope of Work

Task 1 - Storage of Records

The Contractor shall arrange for storage facilities for RRP paper records. These are active records and must be available in the Washington, D.C. metropolitan area. The records must be stored in a secure area and be available for EPA personnel within 24 hours. When directed by the Contracting Officer Representative (COR), the Contractor shall arrange for pickup of additional records from within another location in the Washington, D.C. area. The Contractor shall maintain the existing filing methodology and file any new records accordingly.

Task 2 - Cleaning Verification Cards

When directed by the COR, the Contractor shall provide Cleaning Verification Cards that meet the quality control standards previously developed. The cards shall be shipped to the National Lead Information Center in Rochester, NY. It is anticipated that the cards will be produced in batches of 150,000. Assume one batch will be required.

Task 3 - Support of the Outreach Efforts at Conferences and Trade Shows

When directed by the EPA Contracting Officer Representative (COR), the Contractor shall purchase meeting rooms and exhibit space at conferences and trade shows, ship and staff the EPA-provided booth, if needed. These services include shipping the EPA booth to venues and returning it to a location designated by the COR. Also included in this task is paying for incidental fees such as conference venue drapes, delivery charges, etc.

Task 4 - Technical Studies

When directed by the COR, the Contractor shall produce studies on Lead-Based Paint issues. These studies are anticipated to be of short duration, typically less than 30 days. The exact nature of the study and due date will be contained in the technical direction. Anticipated topics are work practices on Public and Commercial Buildings and other rules in development or under consideration, including analyses on the Lead Dust Study and clearance levels.

Task 5 - Revisions to Documents

When directed by the COR, the Contractor shall provide technical support for general lead, mercury and PCBs, and other national program chemicals outreach, including revising and finalizing EPA pamphlets, poster, banners, flyers for web posting or printing, and developing outreach presentations. The Contractor shall produce both and English and Spanish versions of the documents, when directed by the COR.

Task 6 - Lead Outreach Support

When directed by the COR, the Contractor shall provide support for outreach effort to the regulated community on the Renovation, Repair and Painting Rule and/or other regulations or topics related to lead. The Contractor shall help to identify target audiences. This includes finalizing EPA pamphlets, poster, banners, flyers for web posting or printing, developing outreach presentations, translation of existing EPA documents into additional languages, and outreach support to Native American tribes (and other vulnerable communities), , the purchase of mailing lists, USB drives and CDs, , minimal printing and binding of materials (hard copy and

onto USB drives and/or CDs) (within the allowable limits of the contract) to disseminate the materials.

The Contractor shall develop posters, flyers, a resource package, web banners and other education and awareness tools specifically designed to observe National Lead Poisoning Prevention Week (NLPPW) and International Lead Poisoning Prevention Week (ILPPW).

The Contractor shall provide support for activities that encourage non-certified RRP firms to become certified or to renew their RRP firm certification in up to 4 select cities as identified by the EPA COR. Using housing inventory from the U.S. Census 5-year American Community Survey (ACS) 2017 inventory of pre-1979 housing, coupled with metrics on the number of children under 6 years old from the Census data tracking within the geographical areas, and if available, refugee population, determine which cities should be targeted to participate in the project. The activities shall include, but not be limited to, reserving venues to arrange for informational events on RRP for renovators, coordinating with building code officials, hardware stores and national trade associations to encourage those seeking renovation permits to become informed about the RRP rule, developing graphic designs for posters and web banners, radio and TV ads to announce meetings or events on RRP. The Contractor shall work with the EPA COR to determine when and what type of outreach event will be held in each specific city.

Task 7 - National Program Chemicals Support

When directed by the COR, the Contractor shall provide support to other national program chemicals including but not limited to mercury, formaldehyde, and asbestos. The Contractor shall provide technical support for regulatory and non-regulatory activities involving risk reduction and hazard management of national program chemicals. Technical support includes but is not limited to technical studies and investigation supporting risk evaluation and rulemaking, outreach to the regulated community, outreach to the public and support of regulatory and non-regulatory functions. The Contractor shall provide technical support related to manufacturer requests for risk evaluations and for several existing chemicals identified as "high priority" for risk evaluation under TSCA as directed by the EPA COR. This support will involve supporting development of risk evaluation scope documents including researching regulatory histories, identifying conditions of use, interfacing with manufacturers, users and other stakeholders, and developing supporting documents.

III. Deliverables

Tasks 1 to 3. A letter report providing statistics on the activity for the contract period shall be provided. This can be part of the monthly report.

Task 4. A draft and final report as detailed in the technical direction.

Task 5. Electronic (and/or CDs) of the professional print files of the documents ready for printing and/or posting (508-compliant) onto the EPA webpage.

Task 6. A letter report detailing the activities performed. Electronic (and/or USB or CDs) of the professional print files of any documents prepared for printing and/or posting (508-compliant) onto the EPA webpage and distribution.

For the RRP Outreach Program portion of the task, the Contractor shall provide a summary letter report of providing statistics each activity. The letter shall summarize the work completed and shall include what outreach activities occurred and the number of people reached. In addition, the report will include:

- A description of ads printed for each outreach session in each of the cities.
- A description of the actual outreach event held in each of the cities, including the name, location of the venue, date, and time.
- A description of the number of firms contacted and sources used to develop list of renovation firms to contact.
- An analysis of which outreach messages and delivery mechanism were most and least effective.

Task 7. A draft and final report as detailed in the technical direction.

A work plan is not required. A financial plan is required.
A QA/QC plan is required for Tasks 4 and 7. A QA/QC plan is not required for Tasks 1, 2, 3, 5 and 6.
CBI does not apply.

This work assignment relates to Tasks II, III and IV of the current Statement of Work (SOW) of the contract.

IV. Period of Performance:

This work assignment will start on June 13, 2019 and extend through June 12, 2020.

V. Level of Effort

The approximate LOE is 550 professional hours.

VI. EPA Contacts:

Work Assignment Contracting Officer Representative:
Darlene Leonard
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Program Assessment and Outreach Branch (7404T)
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Deputy Contracting Officer Representative:
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US EPA National Program Chemicals Division
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EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-01

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2019 To 06/12/2020 Base Option Period Number 3	Support for Lead Base Paint

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

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- ☐ Incremental Funding

Period of Performance: From 06/13/2019 To 06/12/2020

Comments:
This amendment is to attached a revised checklist. There is no action required from the vendor.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

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Work Assignment Manager Name: Darlene Leonard (Signature) (Date)		Branch/Mail Code: Phone Number: 202-566-0516 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)		Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name: (Signature) (Date)		Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Jody Gosnell (Signature) (Date)		Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-03

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2020	Support for PCB Program
	Base Option Period Number 3	

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2019 To 06/12/2020

Comments:
Initiating Work Assignment on EP-W-16-017. The contractor shall provide a Work Plan within 15 business days

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

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SFO (*Max 2*): ☐

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Authorized Work Assignment Ceiling

Contract Period: 06/13/2016 To 06/12/2020 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Jennifer McLeod (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	703-308-8459
	FAX Number:	
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-3121
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-4353
	FAX Number:	

Statement of Work

Contract Number: EP-W-16-017
Work Assignment: 3-03
Amendment Number:
Title: Technical Support for the PCB Program

Background
This project is a follow-on to WA 3-03. This WA 3-03 will address 7 on-going tasks in support of the PCB program and will be funded incrementally as funding becomes available.

Scope of Work
This WA will cover the following 7 PCB tasks, with those tasks marked as being initially funded in FY19:

Task 1 will involve task management, including work plan development. **This task will be funded in FY19.**

Task 2 will involve sample collection and analysis during on-site PCB disposal or decontamination demonstrations.

Task 3 will involve PCB disposal and decontamination demonstration requiring review of sampling protocols, including stack emissions.

Task 4 will involve providing sampling kits and performance evaluation (PE) samples for PCB demonstrations.

Task 5 will involve compiling the annual PCB reports into spreadsheets and graphs. **This task will be funded in FY19.**

Task 6 will involve PCB notifications and approvals database entry into RCRAInfo.

Task 7 will involve assisting the agency with making potential regulatory changes to the PCB regulations. **This task will be funded in FY19.**

Tasks

Task 1. Task Management
The Contractor shall prepare and submit a work plan. Work under this task shall include participating in project update meetings/teleconferences, preparing the monthly progress reports and other task management.

When Tasks 2 and 4 are funded, this WA will require a Quality Assurance Project Plan (QAPP) and will require the use of TSCA CBI.
Quality Assurance Project Plans (QAPP) are required under the Agency's Quality Assurance Policy CIO-2105, formerly EPA Order 5360.1A2 and implementing guidance CIO-2105-P-01-

0. In addition to abiding by its own Quality Management Plan that has been approved by EPA, all tasks that involve the generation, collection, analysis and use of environmental data must have an approved QAPP prior to the commencement of the work.

All major deliverables (e.g., Technical Support Documents, Study Reports, Study Plans, etc.) must include a discussion of the QA/QC activities that were or shall be performed to support the deliverable. For example, a Technical Support Document or Study Report must include a clear discussion of the quality management strategies that were employed to control and document the quality of data generated and used.

The QAPP does not have to be submitted at the same time as the Technical and Financial Work Plan unless the environmental data activities covered under the QAPP must begin immediately. In many cases, planning for how to perform the work is needed before the QAPP can be prepared and submitted to EPA for approval. For example, under Task 2, when funded, the QAPP will be submitted when appropriate; however, no work involving the generation, collection, analysis and use of environmental data can begin until an EPA approved QAPP is in place.

NOTE: The tasks below represent all the possible items that may be required by EPA to support the PCB cleanup and disposal program. Written technical direction will be provided by the COR which will specify the items and quantities needed for each task.

Task 2. Sample Collection and Analysis

A. EPA will observe on-site the PCB Disposal or Decontamination Demonstrations and will collect samples and transfer the samples to the Contractor. The Contractor shall analyze the samples appropriately, as outlined below.

(1) For analysis of polychlorinated biphenyls (PCBs), the Contractor shall analyze samples for classes of PCB compounds called Aroclor. These compounds include but are not limited to the following:

Aroclor 1242	Aroclor 1260	Aroclor 1016
Aroclor 1254	Aroclor 1264	

(2) For analysis of PCBs, the Contractor shall provide analytical instrument capability and methodologies to analyze and to identify the 209 congeners of polychlorinated biphenyls.

(3) For analysis of PCBs, the Contractor shall provide analytical instrument capability and methodologies to analyze and to identify PCBs, separating and quantitating the identified PCBs in homologs from mono- to deca-chlorinated biphenyls. The analytical standard to be used shall be the Dry Color Manufacturer Association (DCMA) standard or equivalent.

(4) The Contractor shall transmit analytical results of the demonstration samples to EPA in three stages. First, the raw data will be submitted by telephone or email as directed by the COR. These results will assist EPA in determining the efficacy of the new disposal or decontamination technologies. Second, the Contractor shall prepare a draft digital report. Third, after receiving

comments from the COR, the Contractor shall then prepare the final analytical results which incorporate the COR's comments.

(5) The Contractor shall analyze for other pollutants of interest as directed by the COR. For example, PCBs in the U.S. is in short supply. The possibility exists that surrogates for PCBs may necessarily be used during PCB Disposal or Decontamination Demonstration. Should surrogates be used, the Contractor shall analyze samples for the surrogates. An example of a surrogate is trichlorobenzene.

B. Sample Media. The Contractor shall implement analytical methods suitable to the medium of interest. Examples of media include crankcase oil; mineral oil; solvents such as ethylene glycol; soils such as clay, sediment or sand; fly ash; and clinkers.

C. Sampling Kit.

(1) The Contractor shall provide sampling kits (as described in **Task 4**) for each demonstration suitable for the collection of samples of various media, but not limited to bulk solids such as soil; and bulk liquids such as fuel oil, solvents and water.

(2) The Contractor shall provide a sampling kit suitable for the collection and analysis of samples from porous surfaces (concrete, paint) and non-porous surfaces (metal).

D. For thermal technologies including incineration, the Contractor may be requested by the COR to observe the collection of samples from various process streams and obtain split samples for analysis by the Contractor.

E. The Contractor may be requested to provide personnel with appropriate experience and appropriate certificates to take the samples for any of the technologies and any of the media.

F. The Contractor shall submit a preliminary analysis to the COR for review and comment. Upon receipt of the comments the Contractor shall incorporate the comments into the final report.

Task 3. PCB Disposal and Decontamination Demonstration Requiring Review of Sampling Protocols

A. For thermal technologies including incineration, the Contractor may be requested by the COR to review the applicant's demonstration trial burn plan, to determine/plan the work schedule. Contractor should already be familiar with the process and equipment, from previous work with identical incinerator equipment.

B. For thermal technologies including incineration, the Contractor may be requested to determine if the applicants' stack emission sampling protocols to be used during the trial burn comply with EPA standards.

Task 4. Sampling Kit and Performance Evaluation (PE) Samples

The Contractor shall provide, at the direction of the COR, a sampling kit for EPA PCB Disposal or Decontamination technology evaluators. Sampling items are to be shipped in a cooler ranging in size from one (1) gallon to ten (10) gallons, as appropriate. Packing material must be provided and used as appropriate to minimize breakage of items.

At minimum, the following items shall be provided in the shipping cooler:

A. Traceability Log Forms (3 sheets minimum)
B. Quadruplicated bar codes in self-adhering format (3 sheets - 15 codes minimum per sheet). Traceability forms must accommodate bar codes and sample description.
C. Labels for sample containers to identify samples.
D. Disposable gloves (12 pairs minimum)
E. Wide mouth 100 ml. sampling jars, or 40 ml. vials "VOC" sampling type, or a mixture of jars and vials as specified by COR.
F. Spatulas, two medium size, metal
G. One fine tip marker, waterproof
H. Two writing pens, ball point or fine felt tip
I. "Blue ice" or chemical ice pack for sample preservation
J. Evidence tape, 2 feet in length
K. Shipping bill or air bill prepared for shipping samples to Contractor on overnight basis
L. "Zip locking" plastic bag to protect documents
M. Extra sampling containers in case of breakage or process anomaly
N. Paper towels, e.g. "Kimwipes"

Optional items below, which are required at times, specified by the COR, for specific projects:

O. One-liter jars for aqueous samples, quantity to be specified.
P. Wipe Sampling Kit:
   (1) Folded cotton gauze pad (e.g. 4"x4"), inserted in 100 ml wide mouth jar
   (2) Gauze pad saturated with solvent (e.g. hexane)
   (3) Template for wiping 100 centimeter square area or as specified
   (4) Template disposal or reusable, as specified
   (5) Quantity to be specified by COR
   (6) Solvent to be specified by COR
Q. Spoon or other instruments for sampling

Blind PE samples shall be prepared to evaluate laboratory(s) designated by applicants to analyze samples for the demonstration or for commercial operations. The PE sample(s) may be prepared using various media such as sand, oil (e.g., mineral oil dielectric fluid, MODEF), or water and at various concentrations as directed by the COR (e.g., Aroclor 1260 in MODEF, 10 g in flame sealed ampules; one between 15,000 – 18,000 ppm, one between 5 -10 ppm, and one between 0.5 - 2 ppm).

Task 5. Compiling Annual PCB Reports

At the direction of the COR, the Contractor shall:

1) Go through 2018 annual reports (paper or electronic) that are provided by the COR and enter the facilities' data into the Excel spreadsheet file provided by the COR. The data to be entered will include the data described in the background section above.

2) In a document titled "PCB Annual Report Data Issues," provide to the COR a list of any missing data from any facilities, any facilities' whose annual reports the contractor was not able to decipher, and any facilities that reported data in previous years, but did not submit reports for subsequent years.

3) Update any graphs that are in the Excel file that the COR provides with the new data entered.

4) If requested by the COR, follow up with EPA Regional PCB staff or facilities to track down missing, incorrect, or illegible annual reports and make the additions or corrections to the excel spreadsheet and graphs.

Task 6. PCB Database Entry

Several Regions have either an *Access* database or *Excel* spreadsheet containing their PCB notifications and PCB approvals data. Since EPA is moving to a national PCB database in *RCRAInfo*, there is a need to re-enter all the data from the Regional databases/spreadsheets into *RCRAInfo*. In particular, Region 1's database contains 757 entries and about 20 fields that are common to both databases. This task will have the Contractor perform the data entry from the Regional databases/spreadsheets into RCRAInfo, beginning with the Region 1 database.

The Contractor shall enter as much of the PCB data from the Regional databases/spreadsheets into RCRAInfo, within the existing funding limits. Contractor will continue entering data from the Region 1 database as well as other Regional database/spreadsheets as they become available. Contractor will enter the data manually (i.e., typing) and perform a data entry quality assurance check (i.e., every field entered for every site will be double checked for correctness by a separate individual).

Task 7. Potential Regulatory Changes

The Contractor shall provide assistance to update the PCB Regulations to allow for additional extraction and analytical methods and provide other amendments which clarify the regulations. SW-846 methods for PCB extraction which are not allowed for under the 40 CFR Part 761 regulations, such as EPA Method 3541 (or Automated Soxhlet Extraction), should be compared to the existing method in the PCB Regulations – EPA Method 3540C (or Manual Soxhlet Extraction), to demonstrate equivalent or better extraction efficiencies from the newer method.

Data collection and analysis may be needed to justify a potential regulatory change for the allowance of alternate extraction methods. Only when directed, the Contractor shall assist EPA with:

- Compiling reports (e.g., analytical data report, QA/QC summary report, comparison study report);
- Maintaining records and materials generated during the data collection and analysis;
- Reviewing and responding to documents (e.g. ICR, response to comments, OMB review), and
- Collecting materials (e.g., references, the analytical data and QA/QC summary report, the comparison study report, the statistical analysis report, written articles or publications) that support the regulatory change.

This work assignment relates to Tasks I, V, and VII of the current contract statement of work.

Deliverables

Deliverable	Schedule
Task 1: Task Management	Within 30 days of issuance of Work Assignment Amendment, the Contractor shall submit a Work Plan for review and acceptance.
Task 2: Sample Collection and Analysis	Within 2 weeks of receipt of samples, Contractor will provide draft results. Within 3 weeks of the receipt of the samples the Contractor shall provide a draft report of the chemical analysis. After the COR provides comments on the draft report the Contractor shall produce a final report within 30 days of the receipt of the COR's comments.
Task 3: PCB Disposal and Decontamination Demonstration Requiring Review of Sampling Protocols	Within 20 days of receipt of a copy of the permit applicant demonstration plan, the Contractor will review and submit a summary report of the demonstration plan.
Task 4: Sampling Kit and Performance Evaluation (PE) Samples	Within 3 days of request by the COR, the Contractor will ship a sampling kit and /or performance evaluation samples to the demonstration site for use by EPA or its representative.
Task 5: Compiling Annual PCB Reports	The COR will send the necessary reports (~85-100) to the Contractor on or around July 30th, and the Contractor shall update and finalize the excel file by August 30th, if possible. A one- or two-week extension may be granted to the Contractor by the COR if the Contractor cannot meet this deadline.
Task 6: PCB Database Entry	Upon receipt of databases from the Regions, the Contractor shall enter the data into RCRAInfo within 10 days.
Task 7: Potential Regulatory Changes	Within 2 weeks after receiving a draft document pertaining to the potential regulatory change, the Contractor shall review and submit edits and comments. Other tasks will be performed as directed by EPA COR.

Period of Performance

This work assignment will start on the date of the contracting officer's signature and extend through June 13, 2020.

Level of Effort

The approximate LOE for this requirement is **450 hours.**

EPA Contacts

Contracting Officer Representative
Jenny McLeod
1200 Pennsylvania Ave NW
Mail Code 5303P
Washington, DC 20460
Phone: (703) 308-8459

Courier Service Address:
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Room S-6313
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Alternate Contracting Officer Representative
Josh Smeraldi
1200 Pennsylvania Ave NW
Mail Code 5303P
Washington, DC 20460
Phone: (703) 308-0441

Courier Service Address:
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Room S-6341
Arlington, VA 22202

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-04

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2020	Support for Formaldehyde
	Base Option Period Number 3	

Contractor: BATTELLE MEMORIAL INSTITUTE

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Work Assignment Manager Name: Todd Coleman (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-1208
	FAX Number:	
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-3121
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-4353
	FAX Number:	

Contract Number: EP-W-16-017

Work Assignment Number: 3-04

Title: Support for Formaldehyde Compliance Guides and Other Outreach

I. Purpose and Background

To provide EPA ongoing technical support to develop guidance materials for the Formaldehyde Emission Standards for Composite Wood Products regulations. This project is a continuation of work assignment (WA) 0-04 under contract EP-W-16-017. This WA continues the work initiated in WA 0-04 under contract EP-W-16-017. No work shall be duplicated. Note this change is a decrease in level of effort (LOE) hours only.

Title VI of the Toxic Substances Control Act (TSCA Title VI) establishes formaldehyde emissions for composite wood products and requires EPA to promulgate regulations to ensure compliance with these emission standards. EPA has promulgated regulations for TSCA Title VI which have requirements for manufacturers (including importers), fabricators and laminators of composite wood products. Other entities, such as retailers, wholesalers, and distributors are required to sell, supply, or offer for sale, only composite wood products that are compliant with the regulations. The regulations also establish a third-party certification program for composite wood products. The contactor shall translate and revise, as needed, small entity compliance guides, as required by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and other rule compliance-related materials as directed by the contracting officer representative (COR). The contactor shall provide, as directed by the COR, technical and graphical support for final rule implementation outreach including materials for the EPA Formaldehyde Resource Directory (website).

II. Scope of Work:

For all tasks, the contractor shall:

Task 1: Develop a Work Plan

The contractor shall prepare and submit a technical and financial work plan in accordance with the contract requirements.

Task 2: Develop Language Translations for Small Entity Compliance Guides

For each of the final English language Compliance Guides including: 1) third-party certifiers and accreditation bodies, 2) panel producers, 3) importers, distributors and retailers, and 4) fabricators (including laminators), provide up to 5 language translations, as needed and as directed by the COR. The final Compliance Guides must be in compliance with section 508 of the Rehabilitation Act.

Task 3: Provide Technical Support for EPA Formaldehyde Resource Directory (website)

The contractor shall provide support, as directed by the COR, for technical and graphical materials related to the Formaldehyde Emission Standards from Composite Wood Products final rule implementation and compliance including materials for the EPA Formaldehyde website.

III. Deliverables:

For all deliverables, the contractor shall:

Task 1: Submit a work plan within 30 working days of receipt of work assignment.

Task 2: Provide the COR revised written translations, in a language directed by the COR, of the four English language Compliance Guides within 30 working days after being tasked by the COR. The files shall be professional print-ready files and suitable for EPA web publication. The final translated Compliance Guides must be in compliance with section 508 of the Rehabilitation Act.

Task 3: As directed by the COR provide graphics, displays, forms, etc., for print or for the EPA Formaldehyde website.

A work plan is required.

A QA/QC plan is not required since no data collection applies.

CBI does not apply.

This work assignment relates to Tasks III, and IV of the current Statement of Work (SOW) of the contract. The work assignment shall start upon the Contracting Officer's signature and extend to June 12, 2020.

The Approximate Level of Effort: 90 hours

Contracting Officer Representative:
Todd Coleman
Coleman.todd@epa.gov
202-564-1208

Deputy Contracting Officer Representative:
Robert Courtnage
courtnage.robert@epa.gov
202-566-1081

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-06

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2020 Base Option Period Number 3	Chemical Hazard and Exposure

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2019 To 06/12/2020

Comments:
Initiating Work Assignment on EP-W-16-017. The contractor shall provide a Work Plan within 15 business days

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 06/13/2016 To 06/12/2020 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Jeffrey Taylor (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-8828 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:

WORK ASSIGNMENT
Statement of Work

Title: Chemical Hazard and Exposure Evaluation and Risk Management

Contractor:	Battelle Memorial Institute
Contract Number:	EP-W-16-017
Work Assignment (WA) Number:	3-06
Estimated Period of Performance:	06/13/19 – 06/12/20
Approximate Level of Effort:	1,220 hours
WA COR:	Jeffrey Taylor Phone: 202-564-8828 Email: taylor.jeffrey@epa.gov
Alternate WA COR:	Tyler Lloyd Phone: 202-564-4016 Email: lloyd.tyler@epa.gov
Contract Level COR (CL COR):	Tyrone Thomas OPPT Phone: 202-564-3121 Email: thomas.tyrone@epa.gov

Background:

This work assignment, entitled *Chemical Hazard and Exposure Evaluation and Risk Management*, was developed to provide EPA with support in analyzing primarily existing chemicals and pursuing work for those chemicals that have the highest risk.

EPA's Existing Chemicals Program addresses pollution prevention, risk assessment, hazard and exposure assessment and characterization, and risk management for chemical substances in commercial use. For the chemicals that EPA identifies as high risk, EPA will choose from among many actions that it is authorized to take under the current Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Agency may pursue such regulatory actions as: restricting chemical use through banning its manufacture/import, issuing Significant New Use Rules that require manufacturers/importers to

alert EPA of any new uses, and publishing test rules that require the chemical industry to supply EPA with additional data. Among other options, the Agency will also analyze safer substitute chemicals and consider voluntary phase-outs from the chemical manufacturers.

Purpose and Objectives:

This work assignment continues and expands upon the work initiated under Work Assignment 2-06 of Contract EP-W-16-017. No work performed under previous work assignments will be duplicated under this work assignment.

Tasks and Deliverables:

The WA COR will review all deliverables in draft form and provide revisions or comments to the contractor. The contractor shall prepare the final deliverables incorporating the WA COR's comments. Final deliverables shall be in Microsoft Word or other appropriate electronic format requested.

Contractor personnel shall at all times identify themselves as Contractor employees and shall not present themselves as EPA employees. Furthermore, they shall not represent the views of the U.S. Government, EPA, or its employees. In addition, the Contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead.

The Contractor shall not duplicate any previously performed work. ***Also, the Contractor shall not proceed with any work that requires an approved Information Collection Request (ICR) from the Office of Management and Budget (OMB) until such approval is granted. In addition, the Contractor shall remain in compliance with OMB's Paperwork Reduction Act during the performance of this work assignment.***

Task 1. Work Plan and Task Management

The contractor shall prepare a Work Plan within 15 calendar days of receipt of a work assignment signed by the Contracting Officer (CO). The Work Plan shall outline, describe and include the technical approach, resources, timeline and due dates for deliverables, and a detailed cost estimate by task and a staffing plan.

The WA COR, CL COR and the CO will review the Work Plan. However, only the CO can approve/disapprove, suggest revisions, or change the Work Plan. Official revisions will be given to the contractor by the CO. The contractor shall prepare a revised Work Plan incorporating the CO's comments, if required.

Deliverables and schedule under Task 1

1a. Work Plan within **15** calendar days of receipt of work assignment.

1b. Revised Work Plan within **3** days of receipt of comments from the WA-COR, if required.

Task 2. Quality Assurance Project Plan (QAPP)

The contractor shall submit a QAPP in accordance with the Agency requirements for QAPP (QA/R-5). Detailed information may be found at www.epa.gov/quality. The contractor shall update the QAPP as needed (and in any case, at least once a year). For QAPP revisions, the contractor shall provide a list summarizing the changes from the prior approved QAPP. The QAPP should document the planning, implementation, and assessment procedures for subtasks 3, 5, 6, 7, and 8 in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use.

Task 3. Rulemaking Support

The contractor shall help EPA develop rules, such as TSCA section 4 test rules that secure additional chemical data, section 5 Significant New Use Rules (SNURs) that affect new uses, and section 6 rules that restrict chemicals. Work may include analyzing literature sources or managing information that was developed by EPA or outside entities (e.g., other agencies, states, countries, NGOs, foundations, universities, and companies). The contractor may help collect, organize, and summarize public comments that are submitted by entities such as public interest groups, industry, academia, and others to EPA rulemaking dockets.

Task 4. Meeting & Workshop Support

The contractor shall assist EPA with meeting support by taking notes during meetings, such as at 1-to-2-hour meetings that involve a specific chemical or category of chemicals of concern, or at rulemaking consultation meetings that deal with tribal, small business, and state issues. The contractor will produce the meeting notes and also incorporate any edits to those notes provided by EPA. The contractor will support expert meeting workshops, such as regarding labeling for paint removal chemicals, and these workshops could require the contractor do many services, such as solicit attendees, organize logistics, facilitate the workshop, and summarize the discussions that take place at the workshop.

Task 5. Chemical Prioritization & Work Plan Chemicals

The contractor shall assist EPA with identifying priority chemicals for risk management analysis. Work could include securing lists of chemicals that are being analyzed by: other countries, states within the United States, and EPA or other Federal agencies. The contractor may present information related to hazard, exposure, risk, and different environmental mediums such as air,

water, and soil. The contractor may help EPA identify and take follow-up action on Work Plan chemicals that generally have the greatest risk concerns.

Task 6. Chemical Data Reporting (CDR)

The contractor shall assist EPA with managing chemical data under its CDR. Support can include preparing for the 2020 CDR, working with existing 2016 CDR and 2012 CDR data, helping with Internet and outreach materials, and producing statistics and chemical lists that relate to production volume, companies, industrial processing and use, and consumer and commercial use, among other information.

Task 7. High Production Volume (HPV) Chemical Management

The contractor shall continue to maintain HPV Challenge Program records, and conduct queries on HPV Challenge Program data if needed. The contractor may also perform work with other HPV chemicals.

Task 8. Miscellaneous Hazard, Exposure, and Risk Analyses

The contractor shall conduct analyses regarding other miscellaneous hazard, exposure, and risk management projects as the need arises.

Summary of Deliverables:

Task 1	The contractor shall prepare and submit the work plan in accordance with contract requirements.	
Task 2	Quality Assurance Project Plan (QAPP) • Initial QAPP • Revised QAPP(s)	 • 10 days after WA begins • Prior to work on environmental data activities
Task 3	Rulemaking Support	At WA COR's Request.
Task 4	Meeting & Workshop Support	At WA COR's Request.
Task 5	Chemical Prioritization & Work Plan Chemicals	At WA COR's Request.
Task 6	Chemical Data Reporting (CDR)	At WA COR's Request.
Task 7	HPV Chemical Management	At WA COR's Request.
Task 8	Miscellaneous Hazard, Exposure, & Risk Analyses	At WA COR's Request.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-07

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2021	Predictive Mathematical Modeli
	Base Option Period Number 3	

Contractor: Battelle Memorial Institute

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2019 To 06/12/2020

Comments:
Initiating Work Assignment on EP-W-16-017. The contractor shall provide a Work Plan within 15 business days

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 06/13/2016 To 06/12/2021		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Tony Mcdonald (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-1476 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:

Work Assignment 3-07

1) **Title:** Predictive Mathematical Modeling of Water Contaminant Mixture Data

Contracting Officer Representative

Tony McDonald
Pharmacokinetics Branch
Integrated Systems Toxicology Division
National Health and Environmental Effects Research Laboratory
U.S. Environmental Protection Agency
MD B105-03, 109 T. W. Alexander Drive
Research Triangle Park, NC 27711

Purpose

The Work Assignment is to provide statistical expertise and modeling in support of: a) research designed to understand the potential human health risk(s) associated with exposure to contaminants in water, such as disinfection byproducts (DBPs) and emerging contaminants including but not limited to algal toxins, transformation byproducts and anthropogenic chemicals; b) research designed to improve our ability to create appropriate groups of chemicals for experimental evaluation or risk assessment; and, c) research designed to improve our ability to predict accurately the joint toxic action of chemical mixtures and to determine those components responsible for the majority of the toxicity of the mixture. EPA is conducting this research program under the Safe and Sustainable Water Research (SSWR) National Research Program of the U.S. EPA. Specifically, this Work Assignment is for statistical effort to: review manuscripts intended for peer-reviewed journal publication for technical soundness and accuracy of described models and model outputs based on analyses conducted either during the current work assignment period or previously by Battelle; extend the development and examination of approaches to discern the contributions of individual chemicals and chemical groups to the toxicity of a chemical mixture; conduct statistical analyses to examine the hypothesis that the toxicity of a group of chemicals can be predicted based on knowledge of the dose-response curves of the chemicals contained in the mixture; to develop, where needed, novel approaches, methods and analyses for grouping chemicals; to conduct research to enhance understanding of the joint toxic actions of groups of chemicals; and, to provide expert consultation and advice in interpretation of results of analyses of chemical mixtures and groups.

Background

While the need for toxicological research with both defined and complex mixtures of DBPs and other chemical contaminants of water is well known, the lack of broadly-recognized appropriate statistical methods both to design appropriate experiments and the lack of accepted methods to determine when the effect of defined mixtures of chemicals deviates from that expected under an assumption of dose additivity, has hindered the ability to develop data needed by EPA to

evaluate the potential human health risk that might be associated with exposure to the low levels of the groups of chemicals detected in source waters and the corresponding drinking waters and those chemical groups formed or transformed during disinfection of water (DBPs, including transformation DBPs).

Under the Safe and Sustainable Water National Research Program (SSWR), EPA is conducting a series of studies to understand the toxicity of groups of water contaminants, including Candidate Contaminant List Chemicals, DBPs and transformation DBPs. DBPs and transformation DBPs are chemicals formed or transformed during the disinfection of drinking water. DBPs have been associated with adverse health effects through epidemiological and toxicologic studies. Candidate contaminant list (CCL) chemicals and chemicals of emerging concern (CECs) are of interest, both individually and as groups. Studies at EPA are addressing different source waters and source water characteristics, different drinking waters (CCL and DBP focus) and wastewater treatments (CCL, DBP, CEC focus), with regard to the contaminants present, their concentrations and toxicity, the DBPs formed and their concentrations, and the relative toxic potency of mixture of these chemical contaminants. Understanding those contaminants and contaminant groups that pose the greatest risks to human health will allow risk management and remediation efforts to focus on those that provide the greatest reduction in risk. Integrating toxicological assessments into risk remediation and reduction research provides the opportunity for remediation efforts to focus on those treatments/remedial activities that are most effective at reducing risk.

Predictive models for estimating the effects of contaminants groups will be used, or developed/ revised where necessary and then used, that have the ability to forecast the effects of contaminant groups from single chemical data, creating models that are predictive even when mixture composition changes (fewer chemicals in the mixture, more chemicals in the mixture, the mixing ratio changes as the mixture moves downstream or through the water system). Goals of this program include: development of flexible and accurate predictive models for estimation of the toxicity of contaminant groups that allow for addition and deletion of contaminants and varied specification of chemical concentrations (to enhance usefulness across a spectrum of situations); an improved ability to determine those components responsible for the majority of the toxicity of the mixture; improved understanding of the potential human health risk(s) associated with exposure to environmentally realistic mixtures of contaminants in water; and, the ability to create appropriate groups of chemicals for experimental evaluation or risk assessment.

QA/QC elements consistent with the work requested will be observed during the conduct of this work assignment. These include: 1) before conducting analyses the contractor shall provide the EPA with summary statistics of the data that are being planned for analysis, consisting of sample means, sample standard deviations and sample size for each dose group; 2) potential data quality issues will be presented to EPA as they are identified and prior to proceeding further with analysis; 3) resolution of data quality issues will be documented and approved by EPA before proceeding with analyses. The final report shall include a detailed description of all methods used and the results of analyses conducted, including confidence intervals, statistical significance, multiple comparisons (as appropriate). For any and all final data analyses

conducted, the final program(s) used to analyze the data and the summary statistics of the data generated from the final program shall be provided to EPA with the summary statistics consisting of sample means, sample standard deviations and sample size for each dose group..

Scope of Work

The EPA Contracting Officer Representative will identify the specific deliverables, corresponding delivery dates, and provide additional technical clarification/directives regarding the tasks of the work assignment listed below through technical directives. Each initial deliverable shall be provided to the EPA Contracting Officer Representative in draft form for review and comment. The contractor shall incorporate procedures to ensure that these drafts completely document the methodologies; use appropriate assumptions; are accurate, complete, and as specified in the work assignment or technical direction before providing them to the EPA. The contractor shall incorporate EPA review comments into revisions of the drafts. All drafts and final reports shall be approved by the EPA Contracting Officer Representative. A work plan is required (Task 1). CBI does not apply to this Contracting Officer Representative. This work assignment relates to the current Statement of Work (SOW) of the contract.

Common Elements in Task 3 are:

Review of Background Documentation. The contractor shall review relevant background documentation and materials relevant to this Work Assignment. The EPA will provide reports, publications and draft manuscripts to the contractor. Additionally, the EPA will serve as a resource for relevant literature and background materials relevant to completion of the tasks.

Attend Teleconferences. The contractor shall participate in teleconferences to address any questions that the contractor may have regarding the scope and goals of Tasks 2 and 3 and discuss the data, analytic requirements, relevant background information and available literature. A kick-off teleconference shall be conducted specific to each phase of Tasks 2 and 3. Additionally, the EPA and the contractor shall have conference calls as needed to discuss and clarify technical issues related to the performance of each task. The EPA shall prepare summary notes which clearly summarize the teleconferences within five business days of each call.

Assess Data Quality. The contractor shall assess databases to evaluate their data quality and integrity. The contractor shall identify outliers and questionable data by reviewing data listings and summaries, applying statistical methods, and using graphical methods. The contractor also shall review the data for missing values, censoring patterns, and appropriate units of measure (e.g., milligrams/liter). The contractor shall conduct statistical analyses to assess consistency with or violations of assumptions underlying the proposed analyses (e.g., tests of homogeneity of variance). Prior to use of the data, the contractor shall identify the specific source of the data and also supply EPA with summary data for each dose group proposed for inclusion in the analysis, including the dose level, n, mean and standard deviation and identify any issues with the data such as heterogeneity and proposed transformations.

Develop computer programs. The contractor shall ensure that all databases, computer programs, and the corresponding documentation developed under this contract are accessible to the EPA Contracting Officer Representative, and persons authorized by them. The contractor shall provide this computer programming support to technically support the statistical analysis specified in other areas of this statement of work. All computer programs shall be well documented internally to facilitate EPA's review. Furthermore, the contractor shall use SAS for statistical analysis. At time intervals determined either by the status of the work (e.g. completion of an analysis or final acceptance by a journal of the article describing the analysis) or by the end of Option Period 3, the contractor shall provide all relevant computer programs to EPA.

Documentation. The contractor shall internally document all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code so that results can be replicated even if the originating staff members are no longer available. The contractor shall provide access to this internal documentation upon request by the EPA Contracting Officer Representative. This documentation shall provide the foundation of the documentation of the products to be provided to EPA.

The contractor shall provide documentation for products (i.e. analyses) in Task 3. The contractor shall provide documentation in computer files, and in hardcopy, upon specific request. The contractor shall incorporate EPA comments into revisions of the draft documentation. In all cases, the statistical algorithms and data used to generate results shall be provided electronically as well as in the appendix of the draft reports. Upon EPA review and acceptance of the results and reports, the documentation provided to EPA shall be expanded to include all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code used in accomplishment of the work effort as well as the SAS files themselves.

In any documentation, the contractor shall clearly specify the methods, procedures, considerations, assumptions, relevant citations, data sources, and data that support the results and any recommendations. The contractor also shall document alternative methods, procedures, and assumptions that the contractor considered in the statistical analysis. Further, the documentation shall be labeled with the name of the contractor, the EPA contract number (EPW16017) and the work assignment number (3-07).

2) Tasks

The contractor shall:

Task 1. Workplan and Monthly Progress Report

(A) The Contractor shall prepare a work plan describing tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and, proposed staff names, hours and project roles.

(B) The Contractor shall provide a Table in the Monthly Progress Report that includes a cost summary that includes the hours allocated, the hours used this month and the cumulative hours used. The table shall also include the EPA technical contact, the contractor lead staff, the work assignment number, title and the date.

Memo # and date	Date due	EPA technical Contact	Contractor lead staff	Topic	Hours		
					Allocated	Used this month	Cum used

Through technical direction the Contracting Officer Representative will identify topics to address, estimated hours for each topic, a deliverables due date, and background such as the names of EPA staff to contact for information.

Task 2. Review of Manuscripts,

The contractor shall provide expert review of manuscripts prepared by the EPA for peer-reviewed publication, focusing on statistical methods, analyses of data and interpretation of such analyses, including figures, tables and text for statistical research conducted under EP-C-05-030, EP-W-09-024 and EP-W-16-017 (the current contract). Manuscripts that are expected to be supplied to the Contractor over the course of Option Period 3 Work Assignment 3-07 are:

- Manuscript titled "Analysis of Proportional Data in Reproductive and Developmental Toxicity Studies: Comparison of Sensitivities of Logit Transformation, Arcsine Square Root Transformation, and Nonparametric Analysis". This manuscript has undergone co-author review and concurrence, EPA internal and clearance review and is now at the journal. The extent of the review will depend on the comments received from the journal, but those best handled by the Contractor are not expected to be extensive.
- Manuscript titled "Stability in Chemical Composition of Complex Mixtures of Disinfection By-Products". This manuscript has undergone two rounds of review by the principal authors and is expected to need minimal effort by Battelle before review by all co-authors. The questions and comments received at the co-author, EPA internal, EPA clearance and journal review that focus on the statistical methodology and analysis, will determine the level of effort needed.

Several other manuscripts are expected to be prepared during Option Period 3 WA 3-07 with the involvement and co-authorship (with authorship decisions based on the NHEERL authorship guidelines) of the Contractor. These will result from the analyses conducted in Task 3 and include

- A manuscript describing the results of the dose additivity assessment of the six possible binary combinations of the four regulated trihalomethanes.
- A manuscript describing the results of the Expected Component Analyses of seven HAA mixtures in the CHO assay (including the underlying dose additivity evaluations conducted earlier)

The timeline for these papers depends on the outcome of the analyses being conducted in Task 3,

Option Period 3, WA3-07.

Task 3. Determine Consistency with Dose Addition and Estimate the Contribution(s) of Individual Chemicals and Chemical Groups to the Toxicity of a Chemical Mixture

Task 3 is the centerpiece of Option Period 3 WA 3-07. In this task, the contractor shall provide expert consultation with regard to mixtures analyses and, as directed, conduct statistical analyses to evaluate consistency with dose addition and estimate the contribution(s) of individual chemicals and chemical groups to the toxicity of a chemical mixture. These expert judgemets and analyses shall be conducted using data and reports furnished by the U.S. EPA. The contractor shall also provide expert consultation that provides insights into the interpretation of the results of statistical analyses of mixtures data.

3.A. Modeling Haloacetic Acid (HAA) Mixture Data Collected in Chinese Hamster Ovary Cells.

Task 3.A effort involves data analyses focused on determination of the expected component contribution score for the individual haloacetic acids (HAAs) contained in 7 mixtures. Three are mixtures of the five regulated HAAs at a 1:1 mixing ratio, a mixing ratio representative of chlorination and a mixing ratio representative of pre-ozonation/post-chlorination. Three are mixtures of the nine commonly measured HAAs (these nine include the five regulated HAAs) at mixing ratios equivalent to the five HAA mixtures (1:1, chlorination, pre-ozonation/post-chlorination). There is one mixture (at a 1:1 mixing ratio) of a ten HAA mixture (the nine HAAs with the addition of iodoacetic acid). The first phase of this work was completed under contract # EP-W-09-024 Option Period 4 WA 4-03. Review of the first phase results resulted in additional work that was recently started in Option Period 2 WA 2-07 and will resume in Option Period 3 WA 3-07 at the point where the work ended in Option Period 2 WA 2-07.

- Use DCA as the Index Chemical at both the EC20 and the EC50 for all 7 HAA mixtures (the three 5-HAA mixtures, the three 9-HAA mixtures and the one 10-HAA mixture)
- Use CA as the Index Chemical at both the EC20 and the EC50 for all 7 HAA mixtures (the three 5-HAA mixtures, the three 9-HAA mixtures and the one 10-HAA mixture)
- Use DBA as the Index Chemical at both the EC20 and the EC50 for all 7 HAA mixtures (the three 5-HAA mixtures, the three 9-HAA mixtures and the one 10-HAA mixture)
- Use TBA as the Index Chemical at both the EC20 and the EC50 for 4 of the HAA mixtures (the three 9-HAA mixtures and the one 10-HAA mixture)
- For only the 10 HAA mixture use IAA as the Index Chemical at both the EC20 and the EC50.

3.B. Statistical Analysis of THM mixture data collected in Mice

Task 3.B effort examines selected aspects of the modeling work on THM mixtures in mice done under EP-C-05-030 including re-runs of the SAS programs whose results are the subject of the

earlier reports. There are two main parts to this work: 1) homogeneity of variances; and 2) Lambda, smooth additivity model (SAM) and threshold additivity model (TAM). Additionally, the contractor shall: review their previous work to become familiar with the issues and the data. Review of the first phase results resulted in additional work that was recently started in WA-2-07 and WA-3-07 will resume at the point where the work ended in WA 2-07.

- Homogeneity of Variances. Looking at the results of the previous analyses, an outstanding question is whether the variability in the response data is sufficiently high to create issues due to non-homogeneity of variances. The contractor shall:
  - Conduct statistical tests for homogeneity of variance for all binary data sets. These results will be used in consultation with and concurrence from EPA regarding whether transformation of the response data is appropriate.
  - If the decision is to transform, log10 is suggested, followed by another round of testing for homogeneity of variances.
  - It is suggested that this be done in advance of the lambda, smooth additivity and threshold additivity modeling based on the idea that the homogeneity of variance testing does not require identification of lambda and this order will save time and effort.
- Lambda, smooth additivity model (SAM) and threshold additivity model (TAM) modeling. In the earlier analyses, Battelle based estimation of lambda on the threshold additivity model (TAM). During the subsequent dose-response modeling, when the TAM did not fit the data, an alternative model, the non-threshold smooth additivity model (SAM), was used. The SAM was the same model without the threshold parameter, and it used the same lambda estimate as the TAM. A more recent preliminary investigation of departures from dose additivity was conducted using the SAM only (via SAS statistical analysis software). An outstanding question is whether it is better to use the SAM or the TAM. The contractor shall:
  - articulate the criteria used for selection of lambda.
  - Re-run the SAS programs for all binary data sets, using either the transformed or untransformed data, based on the outcomes and decisions made in the Homogeneity of Variances work (described just above), to determine the lambda values for the SAM. Then, run the SAM using that lambda. If transformed data are used, lambda identification will need to be done with the transformed data for the TAM and then run the TAM using the transformed data lambda.
  - Prepare a table that lists the AIC values of the SAM and TAM models for each mixture. Using this table, consult with EPA about whether either SAM or TAM should be used consistently for all mixtures or if some mixtures are better characterized by SAMs and others by TAM.
  - Based on the results of the re-running of the SAS programs, Wald-type overall tests of additivity (or an alternative) followed by individual dose group tests (as indicated by the overall test) may be called for. These analyses may or may not be needed based on the results in the earlier steps.

3.C. Statistical Analysis of HAA Mixture Data Collected in Whole Embryo Cultures

Task 3.C is a continuation of work started under Option Period 2 WA 2-07 and work will resume in Option Period 3 WA 3-07 where work in Option Period 2 WA 2-07 ended. The toxicity assay is a whole embryo culture assay. There are six endpoints of interest from the whole embryo cell culture assay: normal; dysmorphic, cranial NT, arch 1, heart, final somites. Based are the results of the Normal endpoint, two more endpoints may be analyzed; and, based on the analysis decisions made in 3.B. (Modeling of THM Binary Mixtures), up to three more endpoints may be evaluated.

Three mixtures were tested. The three mixtures are related in that each is a mixture of up to nine haloacetic acids (HAAs). The nine haloacetic acids are: chloroacetic acid, dichloroacetic acid, trichloroacetic acid, bromoacetic acid, dibromoacetic acid, tribromoacetic acid, bromochloroacetic acid, bromodichloroacetic acid and dibromochloroacetic acid. There are concentration response curves for each of these individual haloacetic acids. Mixture LBM is the mixture of these nine haloacetic acids representative of the mixing ratio (the relative proportions) in low bromide source water disinfected by chlorination. The LBM mixture contains only 7 of the 9 HAAs, as two of them were not detected under low bromide conditions (the 2 that are absent are bromoacetic acid and dibromoacetic acid). Mixture MBM is the mixture of these nine haloacetic acids representative of the mixing ratio (the relative proportions) of the 9 that are present in medium bromide source water disinfected by chlorination. The MBM mixture contains all 9 of the HAAs. Mixture HBM is the mixture of these nine haloacetic acids representative of the mixing ratio (the relative proportions) of the 9 that are present in high bromide source water disinfected by chlorination. The HBM mixture contains 8 of the 9 HAAs as one of them was not detected under high bromide conditions (the one that was not detected was chloroacetic acid). The mixing ratios of the three mixtures (LBM, MBM and HBM) are different, so each one is a unique ray, both in the number of HAAs contained in the mixture (7,8,9 for LBM, HBM and MBM, respectively) and in the proportions of the HAAs relative to one another. There are concentration response curves for each of the three mixture rays (LBM, MBM, HBM).

This effort will complete the analyses that focused on the dose addition and expected component contribution score methodology (described in Hertzberg et al 2013, *Toxicology*, 2013, 313:134-144). In addition, the the contractor shall determine, whether predictions of mixture effect, made under dose addition assumptions and models or predictions of mixture toxicity made under independent action assumptions or models or predictions of mixture toxicity made using integrated addition methods (see for example Rider et al, 2008, *Int J Androl.* 31(2):249-62) more closely approximate the observed mixture response. The contractor shall also consider an analysis methodology similar to that described in detail by Altenburger et al., 2000 (*Environ Toxicology Chemistry*, 19(9): 2341–2347) where the 'best fitting model' of each chemical and mixture is used in the analysis.

3.D. Modeling and Evaluation of 9 HAA Mixture Data collected in a Stem Cell Assay

Task 3.D. will examine the effect of the same mixtures described under the third effort (the

LBM, MBM and HBM) HAA mixtures in a different toxicity assay. The toxicity assay is a mouse embryonic stem cell adherent call differentiation and cytotoxicity assay. There are two endpoints in the assays: reduction in cell number; and, effects on differentiation. The requested structure of this effort is the same as in Task 3.C. Specifically, to analyze these two endpoints for dose addition and to calculate the expected component contribution score based on the methodologies described in Hertzberg et al (2013). Following this, the contractor shall determine, whether predictions of mixture effect, made under dose addition assumptions and models or predictions of mixture toxicity made under independent action assumptions or models or predictions of mixture toxicity made using integrated addition methods (see for example Rider et al, 2008, *Int J Androl.* 31(2):249-62) more closely approximate the observed mixture response. The contractor shall also consider an analysis methodology similar to that described in detail by Altenburger et al., 2000 (*Environ Toxicology Chemistry*, 19(9): 2341–2347) where the 'best fitting model' of each chemical and mixture is used in the analysis.

3) Level of Effort:

The approximate level of effort for this work assignment is 684 professional hours. Clerical hours are not included.

4) OTHER REQUIREMENTS

The contractor shall provide written notification to the Contracting Officer Representative when 75 percent of the hours and/or funds have been spent on this work assignment.

The contractor also shall immediately contact the EPA Contracting Officer Representative to discuss any problems that may adversely affect the work on this work assignment.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-10

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2020	New Chemical Program Support
	Base Option Period Number 3	

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2019 To 06/12/2020

Comments:
Initiating Work Assignment on EP-W-16-017. The contractor shall provide a Work Plan within 15 business days

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 06/13/2016 To 06/12/2020 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Rebecca Cool (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-9138
	FAX Number:	
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-3121
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-4353
	FAX Number:	

Contract Number: EP-W-16-017

Work Assignment Number: 3-10

Title: New Chemical Program Support

Purpose:

This work shall be performed under Battelle Contract EP-W-16-017, Task III Technical Program Support-General Support. This work assignment provides support to the New Chemical Program (NCP) in processing of Pre- Manufacturer Notices (PMNs). No work performed under previous work assignments will be duplicated under this work assignment.

I. Background:

This work assignment, entitled *New Chemicals Program Support,* is to provide EPA with support to expedite the processing of the Pre-Manufacturer Notices (PMNs) to reduce the backlog and provide support brought about by the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. This law became effective immediately upon being signed on June 22, 2016. The activities listed below will be an ongoing effort to: Provide PMN Status Tracking, Draft Letters and Consent Orders, Draft documentation needed for Significant New Use Rules (SNURs) and Statement on Administrator Finding to be published in the Federal register. Populate the Pre- Notice Communications Database, Provide Administrative Support to the New Chemicals Ad HOC Committee, and Provide Miscellaneous Administrative Support to the New Chemicals Program as the program changes to implement the new law.

EPA's New Chemicals Program is required to review and make an affirmative determination of risk on new chemical substances submitted for evaluation in premanufacture notices (PMNs) and significant new use notices (SNUNs) before manufacturing, processing and or use can commence. The review evaluates a new chemical substance given the information provided by the submitter of the PMN and the information readily available to EPA to determine if the new chemical substance poses a risk to human health or the environment. This review includes an evaluation of physical and chemical characteristics of the substance, the fate, the human health and environmental hazards, exposures, and risk management to make the affirmative determination of risk. Once the determination is made EPA may regulate the manufacturing, processing and or use of a new chemical substance through a Consent Order and/or Significant New Use Rule (SNUR) which requires manufacturers/importers to alert EPA of any new uses of the new chemical substance. If the determination of not likely to present an unreasonable risk to human health or the environment is made, a notice of the determination must also be published in the Federal Register.

II. Scope of Work:

The Contractor Shall:

Task 1. Work Plan and Monthly Progress Report - Section II.C.3, paras 1-5, page 7; Section II.J, para 1, pages 10-11

(A) Submit a work plan describing tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles.

(B) Provide a table in the Monthly Progress Report with the information shown below:

Memo # and date	Date due	EPA Technical Contact	Contractor lead staff	Topic	Hours Allocated	Used this month	Cum used

Through technical direction, the WAM will identify topics to address, estimated hours for each topic, a deliverables due date, and background such as the names of EPA staff to contact for information.

(C) Some work may require access to TSCA Confidential Business Information. The manager of this work assignment, as well as any staff working on reports that involve TSCA CBI, must be TSCA CBI cleared. They must also take supplementary CBI training designated by the EPA Contracting Officer Representative. Reports based on information drawn from TSCA CBI documents must be submitted to EPA as TSCA CBI, even if the contractor believes they have excluded CBI from the report. This is in addition to complying with all TSCA CBI requirements in the contract and in EPA's *TSCA CBI Protection Manual.*

Task 2. Quality Assurance Project Plan (QAPP) - Section II.C.3, paras 1-5, page 7; Section II.J, para 1, pages 10-11

The contractor shall submit a Quality Assurance Project Plan (QAPP) in accordance with the Agency requirements for QAPP (QA/R-5). Detailed information may be found at www.epa.gov/quality. The contractor shall update the QAPP as needed (and in any case, at least once a year). For QAPP revisions, the contractor shall provide a list summarizing changes from the prior approved QAPP.

Task 3. Document Sanitization- Section II.C.3, paras 1-5, page 7; Section II.J, para 1, pages 10-11

The contractor shall sanitize documents by removing Confidential Business Information (CBI) from Risk Assessment Division (RAD) Section 5 Risk Assessment documents. This will increasingly be asked for by companies as EPA eliminates the practice of sending Action Letters immediately drafting Consent Orders

to be sent to PMN submitters upon finalization of the affirmative risk finding and development of risk management options.

Task 4. Tracking Support- Section II.C.3, paras 1-5, page 7; Section II.J, para 1, pages 10-11
Complete simple spreadsheet created by NCP to track progress of eliminating the back log of cases as well as tracking the completion of information requests sent by PMs to be completed by RAD.
PMs will provide the status/ milestones to be tracked and added to the spreadsheet.

Task 5. Consent Order and SNUR Development - Section II.C.3, paras 1-5, page 7; Section II.J, para 1, pages 10-11
Provide support in developing draft TSCA section 5(e) Consent Orders and SNURs.
After collecting documentation from the Program Manager (PM) to include briefing papers, draft action letters, and other correspondence as well as data and information in PMN Gold and submitted PMNs, draft Consent Orders and SNURS. Drafts will be developed from boiler plates following instructions and using the information collected. After Draft is completed review with PM and prepare printed document for review and signature.

Task 6. Miscellaneous Administrative Support- Section II.C.3, paras 1-5, page 7; Section II.J, para 1, pages 10-11
Provide miscellaneous support to the New Chemicals Program as needed, which may include preparation, scanning, shredding, uploading etc. of documents and file; database creation, population and maintenance; document control; completing information requests from management; and tracking progress of work effort to eliminate backlog of cases and information requests from Program Managers to the Risk Assessment Division.

Task 7. Determination Support - Section II.C.3, paras 1-5, page 7; Section II.J, para 1, pages 10-11
Provide support, to make available to the public, all underlying documents supporting EPA's risk determinations. This support will include sanitization of the determination and related support documents by removing Confidential Business Information (CBI); preparation of documents and language such as preambles and the statement of finding developed from boiler plates, following instructions and using the information in the determination and support documents; uploading documents into the appropriate public docket; and miscellaneous related support.

III. Deliverables:

Task 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements.

Task 2.	Quality Assurance Project Plan (QAPP) • Initial QAPP • Revised QAPP(s)	• 10 days after WA begins • Prior to work on environmental data activities
Task 3.	Document Sanitization	At WAM's Request.
Task 4.	Consent Order and SNUR Development	At WAM's Request.
Task 5.	Miscellaneous Administrative Support	At WAM's Request.
Task 6.	Determination Support	At WAM's Request.

- **A Quality Assurance Project Plan (QAPP) is necessary.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
- **CBI does apply.**
- **Contractor personnel shall at all times identify themselves as contractor employees and shall not present themselves as EPA employees. Furthermore, they shall not represent views of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences**.

IV. Period of Performance:

This Work Assignment will start with the date of the Contracting Officer's signature and extend through - June 12, 2020.

V. Level of Effort:

The approximate level of effort for this work assignment is 3937 professional hours.

VI. EPA Contacts:

Contracting Officer Representative

Rebecca Cool
WJC East Building, Rm 4133-D, MC 7405M
1200 Penn. Ave, NW, Washington, DC 20460
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Cool.Rebecca@epa.gov

Alternate Contracting Officer Representative

Christopher Buckley
WJC East Building, Rm 4133-H, MC 7405M
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EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-10

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2019 To 06/12/2020 Base Option Period Number 3	New Chemical Program Support

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 06/13/2019 To 06/12/2020

Comments:
The purpose of this amendment is to incorporated the revised Work Plan dated 7/23/2019 into the system for Battelle EPW 16017/3-10.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	06/13/2019 To 06/12/2020		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:		Cost/Fee	LOE:
Cumulative Approved:		Cost/Fee	LOE:

Work Assignment Manager Name: Rebecca Cool (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-9138
	FAX Number:	
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-3121
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-4353
	FAX Number:	

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-11

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2020	New Chemical support for SNURS
	Base Option Period Number 3	

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2019 To 06/12/2020

Comments:
Initiating Work Assignment on EP-W-16-017. The contractor shall provide a Work Plan within 15 business days

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
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Authorized Work Assignment Ceiling

Contract Period: 06/13/2016 To 06/12/2020 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Tracey Klosterman (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-2209
	FAX Number:	
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-3121
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-4353
	FAX Number:	

STATEMENT OF WORK

Contract Number: EP-W-16-017

Work Assignment: 3-11

Work Assignment (WA) Title: New Chemical Program Support for Significant New Use Rules, Consent Orders, and other New Chemical Regulatory Activities

Contract Officer Representative (COR)
Tracey Klosterman, CITB, CCD, OPPT
Telephone: (202) 564-2209
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Alternate Contract Officer Representative (COR)
Rebecca Cool, NCB, CCD, OPPT
Telephone: (202) 564-9138
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Mailing Address
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Room 4328X, WJC East Building
Washington, DC 20004

BACKGROUND

The Premanufacture Notice (PMN) program is mandated by Section 5 of the Toxic Substances Control Act (TSCA). The law, enacted in 1976, gives the Environmental Protection Agency (EPA) broad authority to identify and control substances that pose a threat to human health or the environment. Anyone who plans to manufacture or import a new chemical substance for a non-exempt commercial purpose is required to provide the EPA with a PMN at least 90 days prior to the activity. EPA's New Chemicals Program (NCP), which is part of the Office of Pollution Prevention and Toxics (OPPT), is responsible for coordinating the review process of PMN submissions and identifying new substances that require regulatory action. The New Chemicals Management Branch (NCMB) in the Chemical Control Division (CCD) of OPPT is responsible for the risk management of new chemicals.

During the Agency's review period, EPA must determine whether the chemical should be regulated because it has insufficient information to make a determination; may present an unreasonable risk; insufficient information to make a reasonable determination; or presents an unreasonable risk to human health or the environment. One method of regulation is for the EPA to enter into a TSCA Section 5 Order with the Company which allows production of the chemical to proceed under specific restrictions. Under the Expedited Follow-up Rule effective October 10, 1989, when a Section 5 Order is issued for a new chemical substance, EPA is obligated to issue a Significant New Use Rule (SNUR) within a limited period of time. Other deadlines exist for previously issued 5(e) Orders and for new chemical substances that pass through new chemical review with a Not Likely to Present an unreasonable risk but are identified as 5(a)(2) SNUR candidates. The purpose of the Significant New Use Rule (SNUR) is to extend regulation of new chemicals beyond the PMN submitter.

In an effort to make TSCA regulatory actions more readily available to other government agencies, as well as the public, CCD will utilize information contained in the CCD Notice Tracking database to create an MS Access Database to populate the ChemView system for generation of Chemview Templates. All information uploaded into the ChemView system would not contain Confidential Business Information (CBI).

The purpose of this work assignment is to provide technical support to EPA for TSCA Section 5 Actions in the areas of: (1) collection, review, and formatting of supporting and documents, (2) coordination of chemical identity verification, (3) data entry of information into the CCD Notice Tracking database, (4) provide technical assistance to EPA CORs in uploading the resulting MS Access Database files into ChemView, (5) conduct QA/QC of information following upload into ChemView, (6) consolidation and organization of documents in accordance with standardized file plans for records management and (7) provide Help Desk support in managing and responding to questions relating to the functionality and content of TSCA Section 5 data in ChemView . This work assignment will involve the use of TSCA Confidential Business Information.

PERIOD OF PERFORMANCE: Date of issuance through June 12, 2020.

LEVEL OF EFFORT (LOE): The approximate LOE for this Work Assignment is 3,250 hours.

Task 1: Work Plan and Task Management

The contractor shall: Prepare and submit a work plan in accordance with the requirements of this contract. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management.

Task 2: Quality Assurance Project Plan (QAPP)

The contractor shall: Create a Quality Assurance Project Plan (QAPP) in accordance with the Agency requirements for QAPP (QA/R-5) that documents the planning, implementation, and assessment procedures in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: https://www.epa.gov/quality and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

Task 3: Collection of Supporting Documents

The contactor shall: Initiate collection of supporting and source documents including PMN submissions, EPA review reports, Federal Register Notices, TSCA Section 5 Orders, and Not Likely Determinations for PMNs identified by the COR in written technical direction. The Contractor shall utilize all available resources, including the CIS and NCR databases - electronic

version of the files from the Confidential Business Information Center (CBIC), PMN Gold Workflow System, the CBI LAN, individual network directories, hard copy files, etc., for collection of the documents. The documents collected in this manner do not contain CBI, however, they are located in a CBI environment. In those instances, when the documents are not located in a CBI environment, they may be located on public websites including, but not limited to Regulations.gov, Pubchem, and HeinOnline.

The contractor shall: Create a pdf copy of all identified documents for which pdf files are not already available. If the documents are not available electronically, the Contractor shall create a scanned image of the document and convert it to a text searchable pdf format. The EPA Contract Officer Representative (COR) shall provide guidance on naming and storage of the collected documents. The Contractor shall notify the Contract Officer Representative (COR) of any files which are missing.

Task 4: Formatting of Supporting Documents

The contractor shall: Provide technical assistance to the COR in formatting of supporting documents as Adobe pdfs. The COR shall provide written guidance on the formatting requirements, including suitable metadata requirements for publication in the ChemView system. Formatted pdf documents must be text searchable to accommodate the functionality within the ChemView system.

The contractor shall: Track the progress of completion of these formatted documents and verify that completed reports have been posted to the correct location. For the signed TSCA Section 5 Orders, the contractor shall notify the COR of any delays in completion of the reports, and to obtain any sanitized orders that are not available. As the EPA contact, the COR is responsible for certifying that all formatted documents are suitable for transmission to the ChemView system.

Task 5: CCD Notice Tracking database

The contractor shall: Use the collected TSCA Section 5 information to review and populate tables within the CCD Notice Tracking database. All identified chemicals shall be entered into the system using the guidance documents provided by the COR. Process will include the completion of a data worksheet, entry of the required data into the appropriate data tables, and QA/QC of the information for quality assurance purposes according to the approved QAPP. Any identified missing or questionable content shall be reported to the COR. Using the information contained in the database, the contractor shall create MS Access database files for upload into the Chemview system. The Chemview workgroup will review all data and uploaded support documents prior to final approval and publication in the public Chemview database.

5.1 Chemical Identity Verification

The contractor shall: Review and capture information from the sanitized documents to populate the chemical identities included in the TSCA Section 5 Submissions, Orders, SNURs or Not Likely Determination. This identity will include the Non-Confidential name, as well as any

public CAS/Accession Number where available. The COR shall provide written guidance on what sources and naming conventions shall be used. Due to the vast number of intended users of the system, the chemical identity requirements may vary depending on the intended report. In instances where multiple names are available for a given chemical, the contractor shall provide what information is available, and the EPA COR will coordinate verification of the suitable names.

The contractor shall: Use the biannually updated TSCA Inventory to update chemical identities for Section 5 data in ChemView and collect and record chemical identity information for TSCA Section 5 Actions reportable under TSCA Section 12(b).

5.2 Database Data Entry

The contractor shall: Use the non-confidential documents collected, and guidance provided by the COR to enter data into the CCD Notice Tracking database. The written guidance shall detail the specific fields, formatting requirements, and examples of where the information can be found for each data field. Any questions should be posed to the COR as soon as possible to allow additional guidance to be provided.

In addition, the database contains a "Comment" field designed for the contractor to enter any comments, observations, or notes they wish the COR to review. This will allow for a formal accounting of what information was exchanged and allow for future improvements to guidance documents and/or enhancements to the database. All edits to the database shall be at the direction of the COR.

5.3 Report Generation

The contractor shall: Assist the EPA COR in creation of various reports using the export functions of the CCD Notice Tracking database. The contractor shall coordinate with the COR the procedures for generation of the reports and any formatting requirements that may be needed.

Task 6: QA/QC of ChemView System Content

The contractor shall: Assist the EPA COR in review of the current ChemView content in comparison to the New Chemicals Status and Determinations Tables, as well as verification of the accuracy of all data and links contained within each EPA Action output. The contractor shall report weekly on any findings and deliver all requisite information necessary for addressing the error.

Task 7: Records Management

The Contractor shall: Assist the EPA COR in consolidating and organizing documents in accordance with standardized file plans. Prepare eligible records for transfer to the Federal Records Center or retire records directly to the National Archives. Match records to Agency retention schedules and utilize transfer instructions, including instructions for transferring records electronically (ARCIS). Complete necessary electronic forms for transfer.

Task 8: ChemView Help Desk Support

The contractor shall: Assist the EPA COR in managing and addressing ChemView user comments and questions relating to TSCA Section 5. The contractor shall catalogue each incoming inquiry and provide a timely response. The contractor shall report weekly on any activities and deliver all requisite information necessary for addressing the error.

DELIVERABLES: All deliverables shall be submitted to the COR electronically (Adobe pdf).

Task 1.	The contractor shall: Prepare and submit the work plan in accordance with contract requirements.	
Task 2.	Quality Assurance Project Plan (QAPP) • Initial QAPP • Revised QAPP(s)	 • 10 days after WA begins • Prior to work on environmental data activities
Task 3.	Collection of Supporting Documents (Status Update to include including identification of missing documents.)	At COR's Request.
Task 4.	Formatting of Supporting Documents (Monthly status update to include reporting of progress of documents formatted, notification of any quality issues or concerns for these documents, and reporting of documents ready for COR review.)	At COR's Request.
Task 5.	CCD Notice Tracking database and monthly (Monthly status update to include the progress of chemical identity verification, including notation of changes in identities and any updates made to the CCD Notice Tracking database; progress on the completion of the data entry; and report generation.)	At COR's Request.
Task 6.	QA/QC of ChemView System Content (Monthly status update to include the progress of QA/QC of ChemView content, including notation of changes to support documents and any updates made to the CCD Notice Tracking database; progress on the continued review of content; and report generation.)	At COR's Request.

Task 7.	Records Management	According to COR's direction.
Task 8.	ChemView HelpDesk Support	At COR's Request.

ADDITIONAL INFORMATION

- Contractor personnel shall: Identify themselves as contractor employees at all times and shall not present themselves as EPA employees. Furthermore, they shall not represent views of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-11

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2021	
	Base Option Period Number 3	

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 06/13/2019 To 06/12/2020

Comments:
The purpose of this amendment is to change the WACOR to Rebecca Cool.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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3										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 06/13/2016 To 06/12/2021		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Rebecca Cool (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-9138
	FAX Number:	
Project Officer Name: Sheila Brown (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-4651
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Erin M. Ridder (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2155
	FAX Number:	

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-12

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2020	Support for CBI Reviews
	Base Option Period Number 3	

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2019 To 06/12/2020

Comments:
Initiating Work Assignment 3-12 on EP-W-16-017. The contractor shall provide a Work Plan within 15 business days

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
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Authorized Work Assignment Ceiling

Contract Period: 06/13/2016 To 06/12/2020 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Skyler Dobert (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3159 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:

Statement of Work

Contract Number: EP-W-16-017
Work Assignment Number: 3-12

Title: Support for CBI Reviews as Required by TSCA section 14(g)

Purpose:

The Purpose of this Work Assignment is to assemble and extract selected data from TSCA submissions containing information claimed as CBI, and provide a written analysis sufficient to allow for the program office consideration of the validity of the identified CBI claims and then the generation of a recommendation to meet the requirements for a final determination as required under TSCA section 14(g) data related to submitted with new chemical notices and input the information into appropriate databases. The level of detail will vary depending on the type of filing subject to review, and relevant statutory, regulatory and policy considerations.

I. Background:

The Office of Pollution Prevention and Toxics (OPPT) is charged under the Toxic Substances Control Act (TSCA) with reviewing confidential business information (CBI) claims and making recommendations for final determinations concerning the potential validity of these claims. TSCA section 14(g). Because of the statutory mandate that these reviews occur within ninety days of receipt of the documents, identification of the claims, initial data entry, data assembly/extraction, and creation of useful and related information products must occur in a timely fashion in order for it to be used in the statutorily mandated process. These documents will be TSCA submissions directed to the Agency under all provisions of TSCA, as well as follow-up materials, including amendments and substantiations or responses to requests for comments. To address this broad need, the EPA will rely on contractor support to assist in the extraction, summary, and initial analysis/assessment of the data to facilitate the Agency CBI review and determination process.

II. Scope of Work:

Subtask 1. Work Plan and Task Management

The Contractor shall: Submit a work plan that describes tasks, the planned approach, schedule, estimated direct labor hours by labor level, and associated budget. The Contractor may request a meeting (via conference call) with the At Contracting Officer Representative (COR) to seek clarification or to answer any questions prior to the submission of the above work plan.

Upon approval of the work plan, the Contractor shall maintain at least biweekly communication with the At Contracting Officer Representative (COR) regarding the status of the work assignment. Additional points of contact under this work assignment are noted below in VI EPA contacts.

Subtask 2. Quality Assurance Project Plan (QAPP)

A Quality Assurance Project Plan (QAPP) is required. A Quality Assurance Project Plan documents the planning, implementation, and assessment procedures for a particular project, as well as any specific quality assurance and quality control activities. It integrates all the technical and quality aspects of the project in order to provide a "blueprint" for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an

approved Quality Assurance Project Plan. Details for developing a QAPP can be found at: https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf and the Contractor shall be responsible for the development and revisions to the QAPP.

Subtask 3. TSCA CBI reviews

The Contractor shall: Review all documents subject to the TSCA 14(g) CBI review requirements, and extract from each file the data and studies pertinent to the assessment of the CBI claims. These will largely be extracted from substantiations as authorized under the regulations and policies provided by the information submitters.

a. The Contractor shall cause the data to be abstracted and entered into the designated database or spread sheet or template.

b. The Contractor shall also summarize the basis for the submitters' claims of confidentiality, providing specific sources for the summary points (e.g. loss of competitive advantage, Response 3, secret that substance is in commerce, Response 6 etc.) The Contractor shall provide a written analysis sufficient to allow for the Program Office consideration of the validity of the identified CBI claims.

c. The Contractor shall be called to engage in literature searches related to the reviews.

d. The activities and the generated work-products of the Contractor shall be assembled into formats and template of the Program Office's design.

e. The Contractor shall participate in meetings and trainings related to TSCA CBI reviews and incorporate EPA procedural updates in to the workflow as appropriate.

Subtask 4. Confidentiality

The majority of the material related to this activity is claimed by the submitters as TSCA Confidential Business Information, TSCA CBI clearance and adherence to TSCA CBI procedures are required through the duration of the WA.

III. Deliverables:

Subtask 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements. Upon approval of the work plan, the Contractor shall maintain at least biweekly communication with the At Contracting Officer Representative (COR).	• At the start of the WA. • Bi-weekly status meetings with At Contracting Officer Representative (COR).
Subtask 2.	Quality Assurance Project Plan (QAPP) • Initial QAPP • Revised QAPP(s)	• 10 days after WA begins • Prior to work on environmental data activities
Subtask 3.	TSCA CBI reviews	• To be completed within 40 days of receipt of an approved submission. • Following guidance provided by Contracting Officer Representative (COR).
Subtask 4.	The Contractor shall gain and maintain TSCA CBI clearance through the duration of the work assignment	At the start of the WA.

- **EPA will approve the work plan within 45 days.**

A Quality Assurance Project Plan (QAPP) is required. The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a quality assurance project plan (QAPP) following OPPT/EPA guideline. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.

- **A work plan is required.**
- **CBI does apply.**

IV. Period of Performance: the WA will begin on the date of the Contracting Officers Signature and end on 6/12/2019

V. The approximate LOE is: 3000 professional hours.

VI. EPA Contacts:

Primary Contracting Officer Representative
Skyler Dobert
WJC East Building, Rm 4218-C, MC 7408M
1200 Penn. Ave, NW, Washington, DC 20460

Phone: (202) 564-3159
Dobert.skyler@epa,gov

Alternate Contracting Officer Representative
Tyrone Thomas
OCSPP/OPPT/EAD
U.S. Environmental Protection Agency
Washington, DC 20460
(202) 564-3121

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-14

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2020	
	Base Option Period Number 3	

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2019 To 06/12/2020

Comments:
Initiating Work Assignment on EP-W-16-017. The contractor shall provide a Work Plan within 15 business days

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
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Authorized Work Assignment Ceiling

Contract Period: 06/13/2016 To 06/12/2020 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Kristan Markey (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202 564 8716	
	FAX Number:	
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-564-3121	
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-564-4353	
	FAX Number:	

Contract Number: EP-W-16-017

Work Assignment Number: 3-14

Title: EPA Office of Science and Coordination Policy and Office of Pollution and Prevention and Toxics Alternative Testing Strategy, Data Science, and Systematic Review Support

Contracting Officer Representative
Kristan Markey
Office of Science Coordination and Policy
Exposure Assessment Coordination and Policy Division
Tel. (202) 564-8716
Email: markey.kristan@epa.gov

Alternate Contracting Officer Representative
Cory Strope
Office of Pollution Prevention and Toxics
Risk Assessment Division

Tel: (202) 564 4455
Email: strope.cory@epa.gov

Purpose:

This work assignment, *EPA Office of Science and Coordination Policy, Alternative Testing Strategy, Data Science, and Systematic Review Support*, will provide technical support to the Office of Science Coordination and Policy (OSCP) in EPAs Office of Chemical Safety & Pollution Prevention (OCSPP) including the implementation of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy, performance-validation of high throughput (HT) assays, computational models for the estrogen, androgen, and thyroid pathways and cross-species validation studies; and development and prioritization of chemicals in EPA's Endocrine Disruptor Screening Program. No work performed under previous task orders or work assignments will be duplicated under Work Assignment 3-14, EP-W-16-017. However, some of the work is a continuation of EP-W-16-017 Work Assignment 2-14.

I. Level of Effort

The approximate LOE for this work assignment is 2,120 hours. This includes a request for:

- 104 hours for Task 1
- 16 hours for Task 2
- 1300 hours for Task 3
- 700 hours for Task 4.

II. Background

This work assignment will provide technical support in two specific areas:

1. Task 3. Support the implementation of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy under Section 4 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; and
2. Task 4. Support EDSP and OPPT systematic literature reviews for the development of risk evaluations and new alternative methods (NAMs) including performance-based validation of high throughput (HT) assays and computational models.

The Office of Science and Coordination Policy manages EPA's Endocrine Disruptor Screening Program (EDSP). The EDSP was established in 1998 under authorities contained in the 1996 Food Quality Protection Act (FQPA) and the 1996 Safe Drinking Water Act (SDWA) amendments. As mandated by these statutes, the EDSP develops

a screening program to determine whether certain substances may have endocrine activity in humans and wildlife. The US EPA has developed a two-tiered approach for screening chemicals and pesticides. The Tier 1 battery is used to identify substances that have potential to interact with the estrogen, androgen or thyroid hormone pathways. The Tier 2 tests identify and establish dose response information for adverse effects for substances identified in the Tier 1 screening. Beginning in 2015, the EDSP is incorporating ToxCast high throughput screening data and computational models in the prioritization and screening of a chemical's potential to interact with the endocrine system in humans and wildlife for a portion of the Tier 1 battery. This approach will allow nearly 20 times the current number of screenings to be performed while nearly eliminating animal testing, allowing the program to meet its goals with a relatively level budget.

The EPA's EDSP is continuing the development and validation of alternative testing methodologies (i.e., high throughput assays and computational tools) to prioritize and screen chemicals based on potential endocrine bioactivity and exposure--in particular, the estrogen, androgen, or thyroid hormone pathways in humans and wildlife. This increased use of alternative testing methodologies will improve the output of screening results allowing for greater coverage of the endocrine system. EDSP is also supports the incorporation of endocrine endpoints and NAMs into regulatory programs such as TSCA.

I. Statement of Work

Task 1. Work Plan and Task Management

1. The contractor shall prepare and submit a work plan in accordance with the requirements of this contract. The work plan will describe tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management activities.

2. Provide a table in the Monthly Progress Report with the information shown below:

Memo # and date	Date due	EPA technical Contact	Contractor lead staff	Topic	Hours Allocated	Hours used this month	Cumulative hours used

Through technical direction, the COR will identify topics to address, estimated hours for each topic, a deliverables due date, and background such as the names of EPA staff to contact for information.

3. Some work may require access to TSCA Confidential Business Information. The manager of this work assignment, as well as any staff working on reports that involve TSCA CBI, must be TSCA CBI cleared. They must also take supplementary CBI training designated by the EPA COR. Reports based on information drawn from TSCA CBI documents must be submitted to EPA as TSCA CBI, even if the contractor believes they have excluded CBI from the report. This is in addition to complying with all TSCA CBI requirements in the contract and in EPA's TSCA CBI Protection Manual.

4. The contractor shall immediately notify the EPA WA COR if there are any problems that affect the production and delivery of deliverables.

5. The contractor shall provide all deliverables in an electronic format specified by the EPA WA COR (e.g., Word, Excel, Access, HTML) via electronic mail. Unless otherwise specified by the EPA WA COR, Battelle shall provide a secure method for internet transfer of large files.

6. All Deliverables for WA 3-14 are the property of EPA (including any scripts or computer code developed accomplish analyses).

7. The contractor shall format any deliverables intended for posting on an EPA public website to comply with Section 508.

Task 2. Quality Assurance Project Plan (QAPP)

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for subtasks 3 and 4, in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

Task 3. Support the implementation of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy under Section 4 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act

This Task fits specifically under the Contract SOW Task II. Data Analysis (II. 1 – 6).

1. **Data Processing on Existing Chemical Data**. The Contractor shall convert data from TSCA Sections 4, 5, 6, and 8 hazard, exposure, and fate databases not previously converted under WA 2-14 into a machine-readable format (such as ASCII). The contractor shall establish database links for the chemical, guideline, case number, and associated text as pertains to each record.
2. **Data Analysis.** The Contractor shall continue to analyze which tests are most commonly requested, required, and available, and determine trends of data based on chemical classes and other variables as directed by EPA. This knowledge will be used to help optimize future testing strategy (data requests) and to determine tests that would most benefit from alternative testing strategies.
    a. The Contractor shall support the curation, clustering, and prioritization of chemical substances from the TSCA Inventory including analysis of substance nomenclature, chemical structure, and data on physical-chemical properties, use and exposures, and toxicology.
3. **Transformation of OPPT data to OECD Harmonized Templates**. The Contractor shall convert data from TSCA Sections 4, 5, 6, and 8 hazard, exposure, and fate databases into appropriate OECD Harmonized Templates based on Subtask 3.1 and shall upload this data into OPPT's IUCLID installation. As directed by EPA, the Contractor shall identify and implement approaches to extend the IUCLID system, integrate the system into other EPA systems, and develop workflows and interfaces in order to meet EPA's scientific and programmatic needs.

4. **Scientific Platform.** The Contractor shall install and maintain software on the TSCA CBI LAN in Linux and Windows environments in support of this project and for the TSCA NAM Team to support the overall implementation of the TSCA Alternative Testing Strategy. This includes, but is not limited to, R environments and packages, Python environments and packages, relational and non-relational databases (MySQL, PostgreSQL, MongoDB, etc.), internally-facing web applications, etc.
5. **Case Studies.** The Contractor shall support the development and execution of TSCA Alternative Testing Strategy case studies of mutual interest to OPPT and OSCP including analysis of chemical structure, in vivo, in vitro data, and exposure data.

Task 4. Support EDSP and OPPT systematic literature reviews for the development of risk evaluations and new alternative methods (NAMs) including performance-based validation of high throughput (HT) assays and computational models

This Task contains elements under both Task II. Data Analysis (II. 4 - 6) and Task III. Technical Program Support - General Support (III.1, 2, & 4).

1. **EDSP pathway-based systematic literature review pilot and analysis**. The Contractor shall assist EPA with developing and implementing approaches for a pilot on the thyroid-related networks pathway-based systematic literature review. Tasks include articles tagging, title/abstract screening, full-text screening, data extraction, and other annotations as directed by EPA on relevant articles, as well as template design, workflow management, and support of automated approaches.
2. **Data management of Systematic Reviews.** The Contractor shall support the development and implementation systematic review templates (including the use of OECD Harmonized Templates, controlled vocabularies, etc.), reviewer workflows, and reference management in systematic review tools selected by EPA.
3. **Analysis of Systematic Reviews**. The Contractor shall support the data (including data cleaning), statistical (such as meta-analysis of studies), visualization, toxicological, and textual analysis (such as text mining and natural language processing analysis) of systematic reviews and other data streams.

II. Deliverables

The contractor shall provide deliverables as shown in Table 1.

Table 1. Deliverables and Schedule

For tasks 3 & 4, the Work Assignment COR's shall develop and provide specific technical direction to begin scoping the project. The deadlines are intended to be illustrative only for workplan development purposes.

Task	Subtask	Deliverable	Projected Due Dates
Task 1. Work Plan and Task Management		The contractor shall prepare and submit the work plan in accordance with contract requirements.	

Task	Subtask	Deliverable	Projected Due Dates
Task 2. Quality Assurance Project Plan (QAPP)		1. Draft QAPP 2. Final QAPP	Draft: 10 days after WA begins Final: Prior to work on environmental data activities
Task 3. Support the implementation of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy under Section 4 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act	3.1	1. Loading of OPPT data (toxicological, environmental fate, physical-chemical, exposure) into EPA enterprise (MySQL, Postgresql) systems (no report)	At Work Assignment COR's request.
	3.2	1. Naïve TSCA inventory clustering exploration and analysis (report) 2. Naïve TSCA inventory clustering exploration and analysis combined with available in vivo, in vitro, and other TSCA-relevant data (report)	1. 7/30/2019 2. 10/30/2019
	3.3	1. Pilot of existing EPA ecological toxicity data uploaded in the OPPT IUCLID instance (abbreviated report) 2. Development, implementation, and support of user workflows to support new extraction of ecological data directly in OPPT IUCLID instance (no report) 3. Further work and direction following steps 1 & 2	1. 7/30/2019 2. 8/30/2019 3. At Work Assignment COR's request.
	3.4	Installation and management of OPPT CBI LAN Linux and Windows Sandbox and Production Application Software	At Work Assignment COR's request.
	3.5	1. Completion and analysis of two NAM templates as a case study (abbreviated report) 2. Analysis of literature search and data mining of relevant physical-chemical properties, in vitro, and in vivo for inhalation exposures to inform additional structural alerts (including report) 3. Analysis and data mining (including report) of the ecological toxicity as it relates to ECOSAR categories (especially neutral organics) (including report) 4. Inhalation exposure decision-tree model from Deliverable #2 implemented in the QSAR toolbox profiler 5. Additional case studies at Work Assignment COR's request.	1. 8/15/2019 2. 8/15/2019 3. 9/15/2019 4. 9/15/2019 5. At Work Assignment COR's request.

Task	Subtask	Deliverable	Projected Due Dates
Task 4. Support EDSP and OPPT systematic literature reviews for the development of risk evaluations and new alternative methods (NAMs) including performance-based validation of high throughput (HT) assays and computational models	4.1	1. Completion of Thyroid NIS calibration analysis and update (report) 2. Thyroid NIS pilot article review (no report, just completion) 3. Other deliverables at Work Assignment COR's request	1. 6/15/2019 2. 9/30/2019 3. Other deliverables at Work Assignment COR's request
	4.2	1. Completion of Pubertal SR Forms linked to OECD Harmonized Templates and other controlled vocabularies (no report) 2. Other deliverables at Work Assignment COR's request	1. 7/15/2019 2. Other deliverables at Work Assignment COR's request.
	4.3	1. Update Thyroid NIS literature search strategy and ontologies (including report) 2. Thyroid NIS pilot article analysis and NLP model development (including report) 3. Other deliverables at Work Assignment COR's request.	1. 7/15/2019 2. 10/30/2019 3. Other deliverables at Work Assignment COR's request.

1. EPA will approve the work plan within 30 days.
2. **A Quality Assurance Project Plan (QAPP) is required.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
3. This work assignment involves the use of TSCA Confidential Business Information (CBI) for Task 2; otherwise, no CBI is involved.
4. Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent view of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including, but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.

III. Period of Performance

This Work Assignment will start with the date of the Contracting Officer's signature and extend through June 12, 2020.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-14

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2019 To 06/12/2020	3-14
	Base Option Period Number 3	

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 06/13/2019 To 06/12/2020

Comments:
Amendment P00001 adds additional hours for expanded EPA-provided data set EPA Office of Science and Coordination Policy and Office of Pollution and Prevention and Toxics Alternative Testing Strategy, Data

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 06/13/2019 To 06/12/2020 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Kristan Markey (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202 564 8716	
	FAX Number:	
Project Officer Name: Bryan Lobar (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-564-7378	
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Erin M. Ridder (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2155	
	FAX Number:	

Contract Number: EP-W-16-017

Work Assignment Number: 3-14, amendment 1

Title: EPA Office of Science and Coordination Policy and Office of Pollution and Prevention and Toxics Alternative Testing Strategy, Data Science, and Systematic Review Support

Contracting Officer Representative
Kristan Markey
Office of Science Coordination and Policy
Exposure Assessment Coordination and Policy Division
Tel. (202) 564-8716
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Alternate Contracting Officer Representative
Cory Strope
Office of Pollution Prevention and Toxics
Risk Assessment Division

Tel: (202) 564 4455
Email: strope.cory@epa.gov

Purpose:

This work assignment, *EPA Office of Science and Coordination Policy, Alternative Testing Strategy, Data Science, and Systematic Review Support*, will provide technical support to the Office of Science Coordination and Policy (OSCP) in EPAs Office of Chemical Safety & Pollution Prevention (OCSPP) including the implementation of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy, performance-validation of high throughput (HT) assays, computational models for the estrogen, androgen, and thyroid pathways and cross-species validation studies; and development and prioritization of chemicals in EPA's Endocrine Disruptor Screening Program. No work performed under previous task orders or work assignments will be duplicated under Work Assignment 3-14, EP-W-16-017. However, some of the work is a continuation of EP-W-16-017 Work Assignment 2-14.

I. Level of Effort

The approximate LOE for this work assignment is amendment adds 1405 hours to the 2,120 hours originally estimate. This includes a request for an additional:

- 175 = hours for Task 1
- 0 hours for Task 2
- 780 hours for Task 3
- 450 hours for Task 4.

II. Background

This work assignment will provide technical support in two specific areas:

1. Task 3. Support the implementation of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy under Section 4 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; and
2. Task 4. Support EDSP and OPPT systematic literature reviews for the development of risk evaluations and new alternative methods (NAMs) including performance-based validation of high throughput (HT) assays and computational models.

The Office of Science and Coordination Policy manages EPA's Endocrine Disruptor Screening Program (EDSP). The EDSP was established in 1998 under authorities contained in the 1996 Food Quality Protection Act (FQPA)

and the 1996 Safe Drinking Water Act (SDWA) amendments. As mandated by these statutes, the EDSP develops a screening program to determine whether certain substances may have endocrine activity in humans and wildlife. The US EPA has developed a two-tiered approach for screening chemicals and pesticides. The Tier 1 battery is used to identify substances that have potential to interact with the estrogen, androgen or thyroid hormone pathways. The Tier 2 tests identify and establish dose response information for adverse effects for substances identified in the Tier 1 screening. Beginning in 2015, the EDSP is incorporating ToxCast high throughput screening data and computational models in the prioritization and screening of a chemical's potential to interact with the endocrine system in humans and wildlife for a portion of the Tier 1 battery. This approach will allow nearly 20 times the current number of screenings to be performed while nearly eliminating animal testing, allowing the program to meet its goals with a relatively level budget.

The EPA's EDSP is continuing the development and validation of alternative testing methodologies (i.e., high throughput assays and computational tools) to prioritize and screen chemicals based on potential endocrine bioactivity and exposure--in particular, the estrogen, androgen, or thyroid hormone pathways in humans and wildlife. This increased use of alternative testing methodologies will improve the output of screening results allowing for greater coverage of the endocrine system. EDSP is also supports the incorporation of endocrine endpoints and NAMs into regulatory programs such as TSCA.

I. Statement of Work

Task 1. Work Plan and Task Management

1. The contractor shall prepare and submit a work plan in accordance with the requirements of this contract. The work plan will describe tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management activities.

2. Provide a table in the Monthly Progress Report with the information shown below:

Memo # and date	Date due	EPA technical Contact	Contractor lead staff	Topic	Hours Allocated	Hours used this month	Cumulative hours used

Through technical direction, the COR will identify topics to address, estimated hours for each topic, a deliverables due date, and background such as the names of EPA staff to contact for information.

3. Some work may require access to TSCA Confidential Business Information. The manager of this work assignment, as well as any staff working on reports that involve TSCA CBI, must be TSCA CBI cleared. They must also take supplementary CBI training designated by the EPA COR. Reports based on information drawn from TSCA CBI documents must be submitted to EPA as TSCA CBI, even if the contractor believes they have excluded CBI from the report. This is in addition to complying with all TSCA CBI requirements in the contract and in EPA's TSCA CBI Protection Manual.

4. The contractor shall immediately notify the EPA WA COR if there are any problems that affect the

production and delivery of deliverables.

5. The contractor shall provide all deliverables in an electronic format specified by the EPA WA COR (e.g., Word, Excel, Access, HTML) via electronic mail. Unless otherwise specified by the EPA WA COR, Battelle shall provide a secure method for internet transfer of large files.

6. All Deliverables for WA 3-14 are the property of EPA (including any scripts or computer code developed accomplish analyses).

7. The contractor shall format any deliverables intended for posting on an EPA public website to comply with Section 508.

Task 2. Quality Assurance Project Plan (QAPP)

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for subtasks 3 and 4, in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

Task 3. Support the implementation of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy under Section 4 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act

This Task fits specifically under the Contract SOW Task II. Data Analysis (II. 1 – 6).

1. **Data Processing on Existing Chemical Data**. The Contractor shall convert data from TSCA Sections 4, 5, 6, and 8 hazard, exposure, and fate databases not previously converted under WA 2-14 into a machine-readable format (such as ASCII). The contractor shall establish database links for the chemical, guideline, case number, and associated text as pertains to each record.
2. **Data Analysis.** The Contractor shall continue to analyze which tests are most commonly requested, required, and available, and determine trends of data based on chemical classes and other variables as directed by EPA. This knowledge will be used to help optimize future testing strategy (data requests) and to determine tests that would most benefit from alternative testing strategies.
    a. The Contractor shall support the curation, clustering, and prioritization of chemical substances from the TSCA Inventory including analysis of substance nomenclature, chemical structure, and data on physical-chemical properties, use and exposures, and toxicology.
3. **Transformation of OPPT data to OECD Harmonized Templates**. The Contractor shall convert data from TSCA Sections 4, 5, 6, and 8 hazard, exposure, and fate databases into appropriate OECD Harmonized Templates based on Subtask 3.1 and shall upload this data into OPPT's IUCLID installation. As directed by EPA, the Contractor shall identify and implement approaches to extend the IUCLID system, integrate the system into other EPA systems, and develop workflows and interfaces in order to

meet EPA's scientific and programmatic needs.

4. **Scientific Platform.** The Contractor shall install and maintain software on the TSCA CBI LAN in Linux and Windows environments in support of this project and for the TSCA NAM Team to support the overall implementation of the TSCA Alternative Testing Strategy. This includes, but is not limited to, R environments and packages, Python environments and packages, relational and non-relational databases (MySQL, PostgreSQL, MongoDB, etc.), internally-facing web applications, etc.
5. **Case Studies.** The Contractor shall support the development and execution of TSCA Alternative Testing Strategy case studies of mutual interest to OPPT and OSCP including analysis of chemical structure, in vivo, in vitro data, and exposure data.

Task 4. Support EDSP and OPPT systematic literature reviews for the development of risk evaluations and new alternative methods (NAMs) including performance-based validation of high throughput (HT) assays and computational models

This Task contains elements under both Task II. Data Analysis (II. 4 - 6) and Task III. Technical Program Support - General Support (III.1, 2, & 4).

1. **EDSP pathway-based systematic literature review pilot and analysis**. The Contractor shall assist EPA with developing and implementing approaches for a pilot on the thyroid-related networks pathway-based systematic literature review. Tasks include articles tagging, title/abstract screening, full-text screening, data extraction, and other annotations as directed by EPA on relevant articles, as well as template design, workflow management, and support of automated approaches.
2. **Data management of Systematic Reviews.** The Contractor shall support the development and implementation systematic review templates (including the use of OECD Harmonized Templates, controlled vocabularies, etc.), reviewer workflows, and reference management in systematic review tools selected by EPA.
3. **Analysis of Systematic Reviews**. The Contractor shall support the data (including data cleaning), statistical (such as meta-analysis of studies), visualization, toxicological, and textual analysis (such as text mining and natural language processing analysis) of systematic reviews and other data streams.

II. Deliverables

The contractor shall provide deliverables as shown in Table 1.

Table 1. Deliverables and Schedule

For tasks 3 & 4, the Work Assignment COR's shall develop and provide specific technical direction to begin scoping the project. The deadlines are intended to be illustrative only for workplan development purposes.

Task	Subtask	Deliverable	Projected Due Dates
Task 1. Work Plan and Task Management		The contractor shall prepare and submit the work plan in accordance with contract requirements.	

Task	Subtask	Deliverable	Projected Due Dates
Task 2. Quality Assurance Project Plan (QAPP)		1. Draft QAPP 2. Final QAPP	Draft: 10 days after WA begins Final: Prior to work on environmental data activities
Task 3. Support the implementation of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy under Section 4 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act	3.1	1. Loading of OPPT data (toxicological, environmental fate, physical-chemical, exposure) into EPA enterprise (MySQL, Postgresql) systems (no report)	At Work Assignment COR's request.
	3.2	1. Naïve TSCA inventory clustering exploration and analysis (report) 2. Naïve TSCA inventory clustering exploration and analysis combined with available in vivo, in vitro, and other TSCA-relevant data (report)	1. 7/30/2019 2. 10/30/2019
	3.3	1. Pilot of existing EPA ecological toxicity data uploaded in the OPPT IUCLID instance (abbreviated report) 2. Development, implementation, and support of user workflows to support new extraction of ecological data directly in OPPT IUCLID instance (no report) 3. Further work and direction following steps 1 & 2	1. 7/30/2019 2. 8/30/2019 3. At Work Assignment COR's request.
	3.4	Installation and management of OPPT CBI LAN Linux and Windows Sandbox and Production Application Software	At Work Assignment COR's request.
	3.5	1. Completion and analysis of two NAM templates as a case study (abbreviated report) 2. Analysis of literature search and data mining of relevant physical-chemical properties, in vitro, and in vivo for inhalation exposures to inform additional structural alerts (including report) 3. Analysis and data mining (including report) of the ecological toxicity as it relates to ECOSAR categories (especially neutral organics) (including report) 4. Inhalation exposure decision-tree model from Deliverable #2 implemented in the QSAR toolbox profiler 5. Additional case studies at Work Assignment COR's request.	1. 8/15/2019 2. 8/15/2019 3. 9/15/2019 4. 9/15/2019 5. At Work Assignment COR's request.

Task	Subtask	Deliverable	Projected Due Dates
Task 4. Support EDSP and OPPT systematic literature reviews for the development of risk evaluations and new alternative methods (NAMs) including performance-based validation of high throughput (HT) assays and computational models	4.1	1. Completion of Thyroid NIS calibration analysis and update (report) 2. Thyroid NIS pilot article review (no report, just completion) 3. Other deliverables at Work Assignment COR's request	1. 6/15/2019 2. 9/30/2019 3. Other deliverables at Work Assignment COR's request
	4.2	1. Completion of Pubertal SR Forms linked to OECD Harmonized Templates and other controlled vocabularies (no report) 2. Other deliverables at Work Assignment COR's request	1. 7/15/2019 2. Other deliverables at Work Assignment COR's request.
	4.3	1. Update Thyroid NIS literature search strategy and ontologies (including report) 2. Thyroid NIS pilot article analysis and NLP model development (including report) 3. Other deliverables at Work Assignment COR's request.	1. 7/15/2019 2. 10/30/2019 3. Other deliverables at Work Assignment COR's request.

1. EPA will approve the work plan within 30 days.
2. **A Quality Assurance Project Plan (QAPP) is required.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
3. This work assignment involves the use of TSCA Confidential Business Information (CBI) for Task 2; otherwise, no CBI is involved.
4. Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent view of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including, but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.

III. Period of Performance

This Work Assignment will start with the date of the Contracting Officer's signature and extend through June 12, 2020.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-15

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2020 Base Option Period Number 3	Toxic Alternative Testing

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2019 To 06/12/2020

Comments:
Initiating Work Assignment on EP-W-16-017. The contractor shall provide a Work Plan within 15 business days

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 06/13/2016 To 06/12/2020 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Samantha Fontenelle (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-2083 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:

PERFORMANCE WORK STATEMENT
EP-W-16-017
Work Assignment 3-15

TITLE: Fish Tissue Data Migration

WORK ASSIGNMENT COR (WA-COR): Samantha Fontenelle
Standards & Health Protection Division
US EPA (4305T)
Washington DC 20460
202-566-2083
202-566-0409 FAX

Lisa Larimer (Alternate)
202-566-1017
202-566-0409 FAX

PERIOD OF PERFORMANCE: Work Assignment issuance through 06/12/2020

I. Background and Scope of Work

Background

The National Listing of Fish Advisories (NLFA) is a national online database of fish advisories and fish tissue contaminant data collected by states, territories and tribes (hereafter states). It was developed in 1992 and includes advisory information for 50 states, District of Columbia, and the U.S. territories of American Samoa and Guam. It also includes fish tissue contaminant data which served as the basis for state-issued advisories for 48 states. Since 2000, the survey of fish advisories has been performed under an approved ICR for the National Listing of Advisories (OMB Control No. 2040-0226).

Scope of Work

Under this work assignment, the contractor shall assist EPA with the collection, standardization, and migration of state fish tissue contaminant data to the Water Quality Exchange (WQX); and/or assist states with converting their data into the WQX XML format and importing it into WQX.

II. Tasks

Task 1 – Work Plan and Monthly Progress Report

The contractor shall submit a work plan to the Agency within fifteen (15) calendar days of receipt of the WA. The contractor work plan shall describe tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles.

The contractor shall provide a table in the Monthly Progress Report with the information shown below:

Memo # and date	Date due	EPA technical Contact	Contractor lead staff	Topic	Hours		
					Allocated	Used this month	Cum used

Task 2 – Quality Assurance Project Plan (QAPP)

A Quality Assurance Project Plan (QAPP) has been approved by the Contractor's quality assurance/quality control (QA/QC) officer and the EPA/OST QA/QC officers under WA 1-15. This document is a living document and updates shall be made as necessary (e.g., due to changes in scope, key personnel or approach). All deliverables shall include a report describing compliance with the QAPP. The work performed in this PWS shall conform to the Information Quality Guidelines (IQG) Checklist (Attachment A). The completed checklist and final QAPP shall be submitted with the final deliverables.

Task 3 - Data Management Plan

The Data Management Plan was revised under WA 1-15. The Contractor shall update this document as necessary to ensure that the approach for collecting, standardizing, and migrating state fish tissue data is appropriately documented and reproducible.

Task 4 – Tissue Data Collection and Preparing Data for Import

Data quality issues exist with the state fish tissue contaminant data in the NLFA. For this reason as a lack of the required fields for data import into WQX, EPA anticipates that states may elect not to migrate this data to WQX.

Based on written technical direction from the WACOR, the contractor shall assist with collecting new tissue data; standardizing/converting data in flat files (Excel, etc) to WQX-compatible XML files; and addressing any other data related issues. The data review and conversion shall be done to ensure that tissue data migrated to WQX is appropriately formatted to be successfully imported.

For estimating purposes, the Contractor shall assume data from 6 states will be reviewed and converted to an WQX-compatible XML file with required data fields. The Contractor shall support EPA in timeframes specified by the WACOR. This task will require the Contractor work closely with states.

Task 5 –State Fish Tissue Data Import to WQX

The Contractor shall work closely with EPA and states to ensure their tissue data are accurate and complete before they are migrated to WQX. The contractor shall notify EPA and/or the states if there are any import errors if data files fail import and provide recommendations on how to fix errors.

Once tissue data are imported into WQX, the Contractor shall notify each state of its data being successfully imported into WQX. Tasks 4 and 5 activities shall be done in collaboration with each state.

Task 6 – EPA Fish Tissue Data in WQX

The EPA data (OST_SHPD) dataset includes fish tissue data from three studies: GLHHFTS2010, NRSA0809 and NRSA 1314. The contractor shall also support EPA with addressing issues identified with this dataset. This support may include data conversion/mapping to the WQX web XML format and import into WQX.

Task 7 – General Technical Support

The contractor shall provide general technical support which may include responding to inquiries on state tissue data or on the NLFA database; attending monthly fish workgroup calls; preparing or supporting the preparation of presentations; and training state fish program staff on preparing and importing data to WQX using WQX web template. For estimating purposes, the Contractor may assume no more than two presentations will be prepared and three 1-hr training sessions on WQX.

III. Deliverables

The Contractor shall prepare draft deliverable(s) for review by the EPA WACOR in accordance with the deliverable schedule in section IV or by technical direction (TD). In preparing final written deliverables the Contractor shall incorporate written comments from the EPA WACOR and submit the final deliverables in accordance with the deliverable schedule in section IV or TD. The EPA WACOR will review and approve all final deliverables.

Draft and final deliverables including reports, data, databases and maps shall be provided to the WACOR electronically. Electronic files shall be provided in PDF and/or in the original software (Excel, Word). The Contractor shall use Microsoft Office and Adobe Acrobat software for developing all electronic copies of deliverables associated with the work assignment.

IV. Schedule of Deliverables

Task	Deliverable	Schedule
1	Work Plan	Per contract requirements
2	Revised QAPP	As necessary and/or as requested by the WACOR
2	Final QAPP	One month before work assignment completion
2	Information Quality Guidelines	Within 10 business days of completion of the work assignment
3	Revised DMP	As necessary and/or as requested by the WACOR
3	Final DMP	One month before work assignment completion
4	Biweekly updates on status state data collection efforts and data processing/standardization/ conversion to XML format	As requested by the WACOR
5	Status update on state data migration	Within 5 business days of migration of state data
6	Status update on EPA data migration	As requested by the WACOR
7	Presentations, workgroup support	As requested by the WACOR

IV. Reporting:

The Contractor shall include all progress for this WA in the monthly report prepared for this contract. The monthly report shall also include any QA issues encountered and recommendations for resolution. Financial reports shall also be completed as specified in the contract. Financial reports shall also be completed as specified in the contract. The Contractor shall maintain a file of all documentation, including raw data, calculations, assumptions, telephone contacts, and sources of information.

During the period of performance of this work, the contractor shall immediately inform the EPA WACOR by email of any problems that may impede performance along with any corrective actions needed to solve the problem.

V. Contractor Identification:

Contractor personnel shall clearly identify corporate affiliation at the start of any meeting. While attending EPA-sponsored meetings, conferences, symposia, etc. or while on a Government site, Contractor personnel shall wear a badge which identifies the individual as a contractor employee. Contractor personnel are strictly prohibited from acting as a representative of the Agency at meetings, conferences, symposia, etc.

VI. Travel:

No travel is anticipated under this work assignment. However, any travel chargeable to this work assignment shall be allowable only in accordance with the limitation of FAR 31.205-43 and FAR 31.205-46, and must be approved by the EPA Project Officer prior to travel taking place.

VII. Printing:

All copying and printing shall be accomplished within the limitations of the printing clause of the contract.

VIII. Meetings, Conferences, Training Events, Award Ceremonies, and Receptions:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, including the form 5170 for all meetings costing more than $20,000, shall be obtained by the EPA CL COR as needed and provided to the Contracting Officer Work under conference-related activities and expenses shall not occur until this approval is obtained and provided by the EPA CL COR.

ATTACHMENT A

Office of Water Information Quality Guidelines Checklist for Non-*Influential Information*

Office of Water
Information Quality Guidelines Checklist for
Non-Influential Information

- ☐ The information to be disseminated is covered under The Guidelines.
- ☐ The information is in compliance with EPA's Quality System and other related policies.
- ☐ The information is in compliance with Office of Water's Quality Management Plan.
- ☐ The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity.
  - ☐ Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.
  - ☐ Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision.
  - ☐ Utility: the information is useful to the intended users.
- ☐ Meets "transparency" quality standard: the public can understand the source of the information and how conclusions were reached on the information.

_____ _____

Division Director's Signature & Date IQG Officer for OW Signature & Date

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-17

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2020	Superior and Huron Lakewide
	Base Option Period Number 3	

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2019 To 06/12/2020

Comments:
Initiating work assignment on Battelle EPW16017. The contractor shall provide the work plan within 15 business days.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 06/13/2016 To 06/12/2020 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Frank Anscombe (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	312-353-0201
	FAX Number:	
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-3121
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-4353
	FAX Number:	

Performance Work Statement (PWS): Superior and Huron Lakewide Action and Management planning

U.S. Environmental Protection Agency, Region 5, Great Lakes National Program Office

1.0 General

1.1 This work assignment supports environmental planning related to Lakes Superior and Huron.

1.2 **Background:** Lakewide Management under Annex 2 of the GLWQA is led by USEPA in the United States (and Environment and Climate Change Canada (ECCC) in Canada). EPA and ECCC collaborate with U.S. and Canadian environmental and natural resource management agencies, referred to collectively as "the Lake Partnership". The Lake Partnership has two levels: its Working Group and its Management Committee. There is a Lake Partnership for each of the five Lakes.

LAMPs assess environmental conditions on a whole-lake basis and identify restoration and protection priorities. LAMPs are developed for each Great Lake every five years, with the Erie LAMP scheduled for completion during 2018, Lake Michigan in 2019, Superior in 2020, Huron in 2021, and Ontario in 2022.

In addition, the Great Lakes Water Quality Agreement calls for a "Coordinated Science and Monitoring Initiative" (CSMI) for each of the lakes, on a five-year rotating basis. The next Lake Superior CSMI monitoring year is scheduled for 2021, with development of priorities in 2019 and finalization of actions in 2020. The Lake Huron CSMI reporting out is scheduled for 2019, with development of priorities scheduled for 2020, for the next monitoring year of 2022.

The LAMP for Huron was completed circa 2018. This document is well-developed and supplies a robust foundation for an update. It was developed with contract support from Battelle Memorial Institute. The Huron LAMP will be updated during 2021.

In general, the writing style of the CSMI monitoring priorities, matrix and background paper will be concise and use the active voice. The writing will be in plain English to serve federal, state and tribal resource staff and managers. The contractor shall provide document production support, spreadsheets, background papers, and technical editing. The contractor shall also draft an

outline for the next Lake Huron LAMP as well as the 2020 Lake Superior chemical milestones report. EPA's COTR will coordinate within the working group and track contributions from government employees.

1.3 Scope of Work

- Lake Superior CSMI Priority Projects Matrix and background paper
- Workgroup and meeting support for Lake Superior and Lake Huron
- Lake Superior chemical milestones report
- Lake Huron LAMP draft outline
- Outreach and Engagement support

1.4 USEPA Points of Contact

Contracting Officer's Technical Representative (COTR)
Elizabeth Laplante
(312) 353-2694
Laplante.elizabeth@epa.gov

Alternate Contracting Officer Technical Representative (Alternate COTR)
F. Anscombe
(312) 353-0201
Anscombe.frank@epa.gov

Contracting Officer (CO)
Jessica White

2.0 Tasks

2.1: Work plan and work assignment management

2.2: Support to planning CSMI activities

Each of the Lakes has multiple jurisdictions that contribute to LAMP activities.

Every 5th year, one activity is called CSMI, Coordinated Science and Monitoring Initiative.

CSMI generally entails coordination between the US and Canada, and their many affiliated jurisdictions, about what chemical, biological, or terrestrial metrics to sample and analyze, in order to better inform understanding of conditions in the environment.

The contractor shall work with government officials to compile their proposed monitoring parameters. Government stakeholders will share these with the public and invite suggestions and feedback about the monitoring game-plan.

The next CSMI year for Lake Superior will be 2021. To prepare for this, monitoring priorities must be developed, coordinated and finalized during 2020. The contractor shall coordinate conference calls, webinars and meetings of the CSMI workgroup. The contractor shall also summarize monitoring priorities with a 4 to 6 page spreadsheet, with an accompanying short explanatory report. The contractor shall receive inputs from USEPA and produce an integrated document, subject to acceptance by the COR. The contractor shall contribute grammar, readability, and technical editing. Examples of reports may be found attached.

In addition, the contractor shall develop a list of Lake Huron CSMI priorities. These priorities will be listed in a spreadsheet, with accompanying explanation.

2.3: Outreach and Engagement activities

Contractor shall work with the Lake Superior and Lake Huron workgroups, especially the O and E committees, to develop O and E strategies about LAMPs, CSMI, State of the Lake and other GLWQA activities.

The contractor shall support one Superior and one Huron public outreach webinar and one "in-person" meeting, during this performance period.

Contractor will convene conference calls and help develop O and E strategies which will support management processes for these two lakes. After the COR provides an agenda, the contractor shall draft information to share with outside stakeholders.

2.4 Support to lake workgroups

The contractor shall support lake-wide planning by workgroups addressing Lakes Superior and Huron. In general, there are two meetings per calendar year for each lake. Superior meetings are usually three days in duration, plus travel time on either end. Huron is usually two days.

The contractor shall attend one Lake Huron and one Lake Superior meeting during the contractor period. The contractor shall also attend conference calls leading up to these in person sessions. Support will include drafting action items, notes and minutes of meetings.

2.5 Chemical milestones report outline

The contractor shall put together a draft preliminary outline for the chemical milestones report 2020, similar to the most recent milestones report written in 2015.

2.6 Huron LAMP Outline

During early 2020, the Contractor shall draft an outline for the Lake Huron LAMP, based on inputs and comments from the Huron partnership.

3.0 Applicable Documents

Lake Huron LAMP (https://binational.net/2018/04/09/lhlamp-pddplh2/) is the model for technical writing and LAMP development.

4.0 Places of Performance: During 2019-2020, one "in person" meeting each will take place in Superior watershed and one in the watershed of Lake Huron.

5.0 Milestones Table: The contractor shall provide all documents in original source formatting, in addition to MS Word and PDF.

Task	Milestones	Format	Deliverables due
2.1	Workplan and management	Word document and *.PDF document emailed to COR. Upload in FedConnect.	Proposed workplan due within two weeks of start of work assignment
2.2	CSMI monitoring priorities for Lakes Superior and Huron	Word document and *.PDF document emailed to COR. Upload in FedConnect.	Superior1st draft December 2019 2nd draft Superior May 2020 1st draft Huron May 2020
2.3	Outreach and Engagement	Word document and *.PDF document emailed	O&E information for Superior, one meeting and one webinar, by May 2020

		to COR. Upload in FedConnect.	Information for Huron, one meeting and one webinar, May 2020
2.4	Meetings of the two governmental workgroups	Word document and *.PDF document emailed to COR. Upload in FedConnect.	Attend two meetings and provide minutes to memorialize decisions and action items
2.5	Outline chemical milestones report	Word document and *.PDF document emailed to COR. Upload in FedConnect.	May 2020
2.6	Huron LAMP outline	Word document and *.PDF document emailed to COR. Upload in FedConnect.	1st draft 20 days after EPA inputs (circa April 2020).

6.0 Period of Performance: from award thru end of the performance period of the master contract (estimated to be June 2020).